EFFECT OF COLD SALINE SOLUTION AS FINAL IRRIGANT ON POST OPERATIVE PAIN AFTER SINGLE VISIT ROOT CANAL TREATMENT- AN INVIVO STUDY

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DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation titled **"EFFECT OF COLD SALINE SOLUTION AS FINAL IRRIGANT ON POST OPERATIVE PAIN AFTER SINGLE VISIT ROOT CANAL TREATMENT- AN INVIVO STUDY"** is a bonafide and genuine research work carried out by me under the guidance of **Dr. P. SHANKAR, M.D.S.,** Professor, Department of Conservative Dentistry and Endodontics, Ragas Dental College and Hospital, Chennai.

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This is to certify that this dissertation titled **"EFFECT OF COLD SALINE SOLUTION AS FINAL IRRIGANT ON POST OPERATIVE PAIN AFTER ROOT CANAL TREATMENT – AN INVIVO STUDY"** is a bonafide record work done by **Dr. SHRI NANDHINI DEVI. R** under our guidance during her postgraduate study period between 2015 - 2018.

This dissertation is submitted to **THE TAMILNADU Dr. M.G.R. MEDICAL UNIVERSITY**, in partial fulfillment for the degree of **MASTER OF DENTAL SURGERY – CONSERVATIVE DENTISTRY AND ENDODONTICS, BRANCH IV**. It has not been submitted (partial or full) for the award of any other degree or diploma.

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ABBREVIATIONS USED

S.NO	ABBREVIATIONS	DESCRIPTION
1	NaOCL	Sodium hypochlorite
2	EDTA	Ethylenediamine-tetra acetic acid
3	GP	Gutta Percha
4	NO	Nitric oxide
5	PAR	Protease Activating Receptors
6	CGRP	Calcitonin Gene Related Peptide
7	NCV	Nerve conduction velocity
8	PGE 2	Prostaglandin E2
9	HP	Heft Parker
10.	VAS	Visual Analogue scale
11	SPSS	Statistical Package for the Social Sciences
12	COX 2	Cyclo oxygenase 2
13	NSAID	Non Steroidal Anti Inflammatory Drugs
14	%	Percentage
15	°C	Degree Celsius
16	mm	millimetre

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Introduction

INTRODUCTION

Success of endodontic treatment relies on the elimination of microorganisms from the infected root canal system by adequate chemomechanical debridement. This is followed by achieving a hermetic seal through three dimensional obturation. Even with utmost care, some patients experience pain or flare ups during and following the treatment. Pain management during and after root canal treatment is one of the most important aspects of endodontic practice.[68] Postoperative pain is unpleasant and is reported with a high incidence rate ranging between 3 and 58%.[72] Pak and White[57] concluded that the post endodontic pain was most intense in the first 6 hours of the treatment followed by gradual decline in one week. It was 40 % in 24 hours and declined to 11 % in 1 week.[57,8]

The incidence of post operative pain can be due to various factors which include the condition of the pulp and periradicular tissues, microbial factors, inflammatory chemical mediators, cyclic nucleotide changes, preoperative pain, type of tooth involved, changes in the local adaptation and the periapical tissue pressure, patient's psychological factors,and gender.[4,73] In addition, inadequate root canal instrumentation, hyperocclusion, presence of periapical pathology, failure to recognize additional/accessory canals, extrusion of apical debris, and apical patency during canal preparation also contribute to the occurrence of post endodontic pain.[9] Several irrigating solutions or medicaments employed during root canal therapy can evoke pain

sensations by irritating the periapical tissues.[73] This pain may be due to an acute inflammatory response in the periradicular tissues. Pain is a poor indicator of pathology and is considered an unreliable predictor for long term success of treatment. Hence, the integral part of endodontic treatment must include prevention and management of this post endodontic pain.

This post endodontic pain can be prevented in clinical situations by adopting meticulous measures during the endodontic procedure. Each step of root canal therapy must be done with utmost perfection including accurate determination of working length, proper cleaning and shaping, judicious use of intracanal irrigants, and also the use of magnifying devices, such as dental loupes and endodontic microscopes.[15,87] The use of a negative apical pressure irrigation device can also result in a significant reduction of post endodontic pain levels in comparison to conventional needle irrigation.[69] Other strategies for post operative pain management include premedication with prophylactic analgesics and corticosteroids prior to endodontic treatment, administration of long-lasting anaesthesia, and occlusal reduction.[11,20,59,60,64]

Cryotherapy is a long-standing therapeutic technique that has been frequently applied in sports injuries and surgical procedures for pain management and postoperative care in the field of medicine.[79,84] It is effective at reducing edema, pain, inflammation and recovery time.[37,84,48] The term cryotherapy is derived from the Greek word cryos, meaning “cold”. Though, cryotherapy refers to lowering or decreasing the tissue temperature for

therapeutic purposes, it actually does not imply implementing cold but rather extracting heat.[14,32]

The basic physiological responses following the application of either heat or cold are: i) increase or decrease in local blood flow, ii) an increase or decrease in cellular metabolic activity and iii) stimulation or inhibition of neural receptors in the skin and subcutaneous tissues.[88] Physiological and clinical evidence suggest that cold therapy may reduce musculoskeletal pain, muscular spasm, connective tissue distension, nerve conductivity time, inflammation and haemorrhage.[14,88] According to Van't Hoff's law, cold application causes vasoconstriction and slows down cellular metabolism by limiting biochemical reactions which minimize the degree of tissue damage, thus reducing the oxygen demand of cells and limiting the production of free radicals in tissues[52,53]. Vasoconstriction produces antiedema effects. Pain reduction is achieved after temperature reduction because of blockade of the nerve endings resulting from cold application[51]. The intensity of the vasoconstriction effect reaches the highest value at a temperature of 15°C [50] and it has been reported that lowering the body temperature decreases peripheral nerve conduction.[24] Also, changes in tissue pressure activates pain receptors called as thermoreceptors. Cold application activates these thermoreceptors, hence blocking nociception within the spinal cord.[53] The analgesic effect resulting from cryotherapy is mainly produced by a combination of a decreased release of inflammatory chemical mediators.

In dentistry, cold application has been frequently employed for postoperative pain control following intraoral surgical procedures.[38] In recent years, few studies have attempted and reported the intracanal use of cryotherapy in endodontics to reduce post endodontic pain.[6,35,81] Vera.,*et al*. (2016)[81] reported in an in vitro study that, cold saline solution (2.5°C) when used as a final irrigant for 5 mins, resulted in external root surface temperature reduction by more than 10°C and maintained for 4 mins. This may be enough to produce a local anti-inflammatory effect in periradicular tissues. The first clinical study on the effect of intracanal cryotherapy in endodontics was conducted by C Keskin.,*et al*. (2016)[35] to assess the effect of 2.5°C cold saline irrigation as a final irrigant following biomechanical preparation of root canals on postoperative pain in patients with irreversible pulpitis and, reported that, there was a significant pain reduction levels when compared to that of a control group. The authors compared the effect of intracanal cryotherapy by delivering the cold saline solution using conventional needle irrigation with side-vented 31 G NaviTip needle inserted 2 mm short from working length. A recent clinical study was carried out by Al-Nahlawi.,*et al*. (2016)[6] to reveal the effects of intracanal cryotherapy and negative irrigation technique (EndoVac System) on post endodontic pain after vital single visit endodontic treatment. This study showed that intracanal cryotherapy along with negative pressure irrigation system reduced post endodontic pain.

Hence it was decided to do a study on post endodontic pain and thereby validate the following hypothesis , that

- There is no significant reduction in external root surface temperature following final irrigation with cold saline at 2.5° C during endodontic treatment of mandibular premolars invitro, and
- There is no significant difference in post operative pain following final irrigation with cold saline at 2.5° C during endodontic treatment of mandibular premolars , invivo.

Aim and Objectives

AIM AND OBJECTIVES

AIM:

The aim of this study was

- To estimate the changes in external root surface temperature following final irrigation with cold saline at 2.5° C in the root canal of extracted mandibular premolars (invitro).
- To evaluate the effect of root temperature reduction, after using 2.5° C cold saline solution as final irrigant with negative pressure irrigation system, on postendodontic pain after single-visit root canal treatment (invivo).

OBJECTIVES:

INVITRO STUDY TO EVALUATE TEMPERATURE CHANGE

1. To estimate the external root surface temperature in extracted mandibular premolars, prior to endodontic treatment.
2. To evaluate the change in external root surface temperature after using normal saline as final irrigant.
3. To evaluate the change in external root surface temperature after using cold saline at 2.5 °C as final irrigant.

4. To compare the temperature change in extracted mandibular premolars, before and after endodontic treatment with normal saline as final irrigant.
5. To compare the temperature change, before and after endodontic treatment with cold saline at 2.5 °C as final irrigant.
6. To compare the temperature change in extracted mandibular premolars, due to the effect of normal saline and cold saline at 2.5 ° C.
7. To record the values and subject to statistical analysis.

INVIVO STUDY TO EVALUATE THE POST OPERATIVE PAIN FOLLOWING COLD SALINE IRRIGATION

8. To estimate pre operative pain using Heft Parker Visual Analogue Scale (HPVAS) in mandibular premolars with acute irreversible pulpitis.
9. To estimate post operative pain using HPVAS in control group (normal saline used as final irrigant) at the end of 6, 12,24,48 hours, 4 days and 7 days of single visit endodontic treatment.
10. To compare the post operative pain at the end of 6, 12,24,48 hours, 4 days and 7 days in control group (normal saline used as final irrigant).
11. To estimate post operative pain in mandibular premolars at the end of 6, 12,24,48 hours, 4 days and 7 days after endodontic treatment in experimental group (cold saline at 2.5 ° C used as final irrigant).

12. To compare the post operative pain at the end of 6,12,24,48 hours, 4 days and 7 days in experimental group (cold saline at 2.5 ° C used as final irrigant).
13. To compare the number of patients with post operative pain at the end of 6,12,24,48 hours, 4 days and 7 days between control group and experimental group.
14. To record the HPVAS scores and subject to statistical analysis.

Review Of Literature

REVIEW OF LITERATURE

Lisanti V. F et al (1950)[43] evaluated thermal conductivity of dentin. Their study showed thermal conductivity of dentin to be 2.29 X 10^{-3} cal/sec/cm^2/^{0}C/cm.

Simeral W.G. (1951)[74] evaluated thermal conductivity of dental materials. The author reported thermal conductivity of human dentin to be 2.35 X 10^{-3} cal/sec/cm^2/^{0}C/cm, and reported values of 2.81 X 10^{-3} cal/sec/cm^2/^{0}C/cm for zinc phosphate and 2.00 X 10^{-3} cal/sec/cm^2/^{0}C/cm for silicate cements.

Philips RW et al (1954)[63] evaluated the thermal conductivity of dental cement. They measured the thermal conductivity of dentin to be 0.257 X 10^{-3} cal/sec/cm^2/^{0}C/cm. They listed the thermal conductivity of zinc phosphate and silicate cements to be 3.91-5.37 X 10-3 and 0.311-0.388 X 10^{-3} cal/sec/cm^2/^{0}C/cm.

Soyenkoff B.C et al (1958)[76] evaluated thermal Conductivity of Dental Tissues with the Aid of Thermistors . The thermal conductivity of human dentin has been reported 0.96-1.07 X 10^{-3} cal/sec/cm^2/^{0}C/cm, respectively. The thermal conductivity of human enamel has been reported to be 1.55 X 10^{-3} cal/sec/cm^2/^{0}C/cm.

Franz DN et al (1968)[24] evaluated the effects of low temperature on conduction in single myelinated and non-myelinated axons of the feline saphenous nerve. They concluded that non-myelinated axons could conduct

low frequency trains of impulses at temperatures that blocked such activity in myelinated axons. In all axons, high frequency trains of impulses could be completely blocked at temperatures which permitted lower frequency trains to pass uninterrupted.

Bystrom A et al(1985)[15] evaluated the antibacterial effect of irrigating infected root canals with 0.5 and 5 per cent sodium hypochlorite solutions The results indicated that there was no difference between the antibacterial effect of these two solutions. The combined use of EDTA and 5 per cent sodium hypochlorite solution was more efficient than the use of sodium hypochlorite solutions alone. An important observation was that bacteria surviving instrumentation and irrigation rapidly increased in number in the period between appointments when no intracanal medicament was used.

Ruiz HE et al(1987)[70] compared conventional, step-back instrumentation technique with the crown-down pressureless or step-down technique to determine the amount of debris pushed through the apical constriction during root canal preparation. Results indicated that a significantly greater amount of debris was forced periapically in both straight and curved canals when the step-back technique was used. However, neither technique was totally effective in preventing the extrusion of debris during instrumenration.

Genet JM et al (1986)[27] investigated thirteen preoperative and operative factors regarding their association with the incidence of postoperative pain after the first session of root canal treatment. The results of their study showed

that postoperative pain after the first visit occurred in 27 per cent of cases (5 per cent severe and 22 per cent moderate pain). Positive correlation occurred between the incidence of postoperative pain and several factors: the presence of preoperative pain in conjunction with a non-vital pulp; the presence of a radiolucency larger than 5 mm in diameter; the number of root canals of the tooth treated; women reported more postoperative pain than men.

Belitsky RB et al (1987)[15] evaluated and compared the ability of wet ice, dry ice, and cryogenic packs to reduce and maintain the reduction of skin temperature directly under the cooling agent and to determine whether the cooling effect on skin extended beyond the surface area in contact with the cooling agent. The results of their study showed that, after 15 minutes of cold application, mean skin temperatures recorded under wet ice, dry ice, and cryogenic packs decreased 12 degrees, 9.9 degrees, and 7.3 degrees C, respectively. The only significant differences in cooling were between wet ice and dry ice and between wet ice and cryogenic packs. Fifteen minutes after removal of the cold modalities, no significant differences were found in mean skin temperature between wet ice, dry ice, and cryogenic packs. These findings provide valuable information for the use of cryotherapy in the clinical setting

Albashaireh ZS (1988)[2] conducted a prospective study to determine whether there is any significant difference in the incidence of postobturation pain after single and multiple-visit root canal treatment . The canals of all teeth

were prepared and filled by a single operator using the step-back and lateral condensation techniques. The results showed that pain was significantly higher in the multiple-visit RCT group and significantly associated with the treatment of the nonvital pulp. A significantly higher incidence of postobturation pain was found in the multiple-visit group (38%) than in the single-visit group (27%) within 24 h of obturation.

Almekinders LC et al (1993)[5] in an invitro model studied the effects of repetitive motion. The results indicated that repetitive motion induces production of PGE_2.

Mcdowell JH (1994)[48] provided an overview of the physiology of cold, basic principles of cryotherapy, various techniques of cold application, nursing assessment and care for orthopaedic patients.

Ernst Edzard et al (1994)[23] reviewed the effect of clinical effectiveness of analgesic co1d therapy. They suggested that the mechanisms by which cryotherapy might elevate pain threshold include an antinociceptive effect on the gate control system, a decrease in nerve conduction, reduction in muscle spasms, and prevention of edema after injury. They concluded that ice may be useful for a variety of muscuJoskeleta pains, yet the evidence for its efficacy should be established more convincingly.

Al Ani et al (1995)[1] studied the actions of the proteinase-activated-receptor-2 (PAR2)-activating polypeptide, in rat aorta and in gastric

longitudinal muscle preparations. The authors concluded that, like the thrombin receptor, the PAR2 receptor may play a pathophysiologic role in the regulation of vascular and gastric smooth muscle contractility.

Al Omari et al (1995)[7] assessed and compared canal blockages and apical extrusion of dentin debris during canal shaping with eight preparation techniques. The techniques included were standardized, stepback with reaming, stepback with circumferential filing, stepback with anticurvature filing, double-flare, stepdown, crown-down pressureless, and balanced force. Blockages varied significantly among techniques and occurred most frequently in canals prepared with the stepback techniques with anticurvature and circumferential filing and least in the balanced force technique. Apical extrusion occurred , but there were no significant differences in the incidence of extrusion among techniques. The weight of extruded dentin did vary significantly among techniques, with most extrusion occurring with the stepback techniques with circumferential (0.71 mg) and anticurvature (0.69 mg) filing and the least extrusion with the balanced force (0.38 mg) and crown-down pressureless (0.46 mg) techniques. The authors concluded that techniques involving a filing (linear) motion caused significantly more blockages and extruded significantly more apical dentin debris.

Stabholz A et al (1995)[77] evaluated the efficacy of tactile detection of the apical constriction in flared and nonflared root canals . In group 1,a #15 or #20 K-file was used to detect ("feel") the apical constriction. In group 2, Hedstrom

files, Gates Gliden drills #2 to #4, and ultrasonic files were used to enlarge the canal orifice and flare the coronal portion of the root canals before testing the apical constriction. The results of this study showed that the files inserted in preflared root canals had a significantly lower incidence of overextension than those placed in nonflared canals (21% versus 41%). The ability to determine the apical constriction by tactile sensation was significantly increased when the canals were preflared.

Marcus DA et al (1995)[46] presented the important link between altered sex hormones and changes in neurochemicals believed to be responsible for recurring headache syndromes according to the neurobiological theory of migraine.

Swenson C et al (1996)[79] provided an overview of cryotherapy in sports medicine. They have stated that cold increases the pain threshold, the viscosity and the plastic deformation of the tissues but decreases the motor performance. The application of cold decrease the inflammatory reaction in an experimental situation. Cold appears to be effective and harmless. Few complications or side-effects after the use of cold therapy were reported. Prolonged application at very low temperatures should, however, be avoided as this may cause serious side-effects, such as frost-bite and nerve injuries.

Rubinstein R (1997)[69] explored the current status of magnification and illumination in endodontic surgery. The author also discussed the basic

operations of the operating microscope and the various operating positions used in endodontic microsurgery

Rosenberg PA et al (1998)[67] evaluated the effect of occlusal reduction on pain after endodontic instrumentation. Teeth were randomly assigned to 1 of 3 groups: (i) total occlusal reduction, (ii) simulated occlusal reduction (nonfunctional cusp reduction), or (iii) control (occlusion untouched). After canal instrumentation, a questionnaire was used by patients to record pain responses over a 48-hour post-operative period. The authors concluded that occlusal reduction should prevent postoperative pain in those patients whose teeth initially exhibit pulp vitality, percussion sensitivity, preoperative pain, and/or the absence of a periradicular radiolucency.

Dao TT et al (1998)[18] evaluated the potential influence of reproductive hormones on myofascial pain in women. Preliminary results of their study showed that pain levels of oral contraceptives users remained positive across the hormonal cycle, whereas in nonusers, peaks of pain alternated frequently with pain-free periods. These data suggest that pain levels in oral contraceptives users may be more constant than those of nonusers.

Loeser JD et al(1999)[44] provided an overview on pain mechanism. They stated that ageing was associated with an increased likelihood of chronic pain. Despite improved knowledge of underlying mechanisms and better treatments, many people who have chronic pain receive inadequate care.

Steinhoff M et al (2000)[78] in their study found that a large proportion of primary spinal afferent neurons, which express proteinase-activated receptor 2, also contain the proinflammatory neuropeptides calcitonin gene-related peptide and substance P. Trypsin and tryptase directly signal to neurons to stimulate release of these neuropeptides, which mediate inflammatory edema induced by agonists of proteinase-activated receptor 2. This new mechanism of protease-induced neurogenic inflammation may contribute to the proinflammatory effects of mast cells in human disease. Thus, tryptase inhibitors and antagonists of proteinase-activated receptor 2 may be useful anti-inflammatory agents.

Hamilton JR et al (2000)[30] investigated the mechanisms of protease-activated receptor-1 (PAR1) and PAR2-induced relaxation in pre-contracted porcine coronary artery ring preparations and also whether Thrombin and the PAR1-activating peptide SFLLRN caused concentration- and endothelium-dependent relaxation. Their results suggested heterogeneous mechanisms in the NO-independent relaxation to thrombin and peptide activators of PAR1 in the porcine coronary artery.

Menke ER et al (2000)[49] determined if prophylactic etodolac would significantly reduce postendodontic pain, when compared with ibuprofen or placebo. Results showed that prophylactic ibuprofen administration significantly reduced postendodontic pain at 4 and 8 h after initiation of root canal therapy, when compared with etodolac and a placebo. Patients with a

periapical diagnosis of acute apical periodontitis or with a phoenix abscess showed a significant increased need for additional medication after completion of root canal therapy, compared with all other periapical diagnoses.

Garavilla L et al (2001)[26] hypothesized that thrombin cleaves PAR1 on sensory nerves to release substance P (SP), which interacts with the neurokinin 1 receptor (NK1R) on endothelial cells to cause plasma extravasation. They concluded that thrombin cleaves PAR1 on primary spinal afferent neurons to release SP, which activates the NK1R on endothelial cells to stimulate gap formation, extravasation of plasma proteins, and oedema. In intact tissues, neurogenic mechanisms were predominantly responsible for PAR1-induced oedema.

Bartfai T (2001)[13] provided an overview on immunology. He stated that inhibitors of cyclooxygenase-2 that penetrate the blood–brain barrier would be even more efficient painkillers, working to block the oversensitivity to pain that is coordinated by the brain.

Merrick MA (2002)[50] revisited the secondary injury model, to incorporate several current pathophysiologic theories into the model, and to show the need for more direct research examining the model. The conclusions revealed secondary hypoxic injury to be secondary ischemic injury, and several specific mechanisms for ischemic injury were identified. Similarly, secondary injury from mitochondrial failure and other potential mechanisms were identified,

and the role and interaction of these mechanisms in relation to total secondary injury were expanded.

Kimura Yuichi et al (2002)[36] measured the temperature of the root surface during root canal preparation using Er:YAG laser irradiation at 2 Hz and 136 to 184 or 170 to 230 mJ/pulse for 1 min and evaluated the thermal effect on the periodontal region. The temperature of the root surface was monitored using thermocouples throughout the procedure. Their results suggested that the temperature on the root surface increased by less than 6°C at the apical area and by less than 3°C at the central area. A morphological evaluation revealed no carbonization or melting. They concluded that the thermal effect on periodontal tissues during root canal preparation using an Er: YAG laser at less than 230 mJ/pulse for 1 min is minimal.

Rosenberg et al (2002)[68] provided an overview on the procedures used to treat endodontic emergencies in the context of relevant controlled clinical trials and their underlying biological principles.

Reid G et al (2002)[65] investigated the mechanisms of cold transduction in thermoreceptive neurones from rat dorsal root ganglia. They concluded that the cold- and menthol-activated current is the major mechanism responsible for cold-induced depolarisation in DRG neurones, and largely accounts for the known transduction properties of intact cold receptors.

Saeki Y (2002)[71] determined the effect of the application of cold or heat on the sensation of pricking pain based on autonomic responses. Electrical stimulation was applied to the antebrachium or brachium of subjects as an artificial pricking pain, and skin blood flow (BF) and skin conductance level (SCL) at the fingertip were measured. Pain sensation was evaluated using the visual analog scale. Pain stimulation produced a significant increase in SCL and a significant decrease in BF at both the antebrachium and brachium. Application of cold to the stimulation site using an ice-water pack reduced BF and SCL responses and pain sensation. Application of heat using a hot water bottle caused a significant increase in pain sensation and enhancement of BF and SCL responses. The results suggested that application of cold promotes relief of pricking pain sensation and suppression of autonomic responses, and that application of heat has no such effect.

Watkins CA et al(2002)[85] compared the levels of anticipated and experienced pain in patients who received endodontic therapy. They concluded that younger people anticipate and experience higher pain levels. Women are more likely than men to anticipate, but not necessarily experience, higher pain levels. Dentists are more closely attuned to the pain experiences of their female patients.

Ehrmann EH et al (2003)[22] investigated the relationship of postoperative pain to three different medicaments placed in the root canal after a complete biomechanical debridement of the root canal system in patients presenting for

emergency relief of pain. Samples were divided into three groups. Group 1: Ledermix paste , Group 2: calcium hydroxide paste and Group 3: no dressing. They concluded that painful teeth with acute apical periodontitis that had been dressed with Ledermix paste gave rise to less pain than that experienced by patients who had a dressing of calcium hydroxide or no dressing at all. Ledermix is an effective intracanal medicament for the control of postoperative pain associated with acute apical periodontitis, with a rapid onset of pain reduction.

Vergnollen Nathalie (2003)[82] provided an overview on inflammatory response. The author also stated a crucial role for PARs that seemed to emerge from the most recent literature and presented PARs as novel and interesting therapeutic targets for the treatment of inflammation.

Seltzer S (2004)[73] provided an overview on pain in endodontics. A number of hypotheses which caused pain exacerbations were discussed

Ng Yl et al (2004)[54] investigated the prevalence of post-obturation pain after root canal treatment and evaluated the influence of factors affecting the pain experience. They concluded that prevalence of post-obturation pain was high (40.2%). The important prognostic determinants of post-obturation pain were female, molar tooth, size of periapical lesion smaller than 3 mm, history of post-preparation pain or generalized swelling and single-visit treatment.

Carotte P et al (2004)[16] provided an overview on the preparation of root canals. Research into root canal preparation has led to significant changes in instrumentation techniques. Hand files should be manipulated by the balanced-force technique. Recent designs of endodontic instruments have variable tapers giving improved shaping ability. Nickel-titanium rotary instruments will rapidly and safely open the main root canals creating deep space to permit full permeation of irrigant solutions. Practitioners considering changing their endodontic technique are advised to attend hands-on practical courses to gain competence before using these in clinical practice.

Lipski Mariusz et al (2004)[39] measured the temperature rise on the outer root surfaces of teeth during four different root canal obturation techniques. After root canal cleaning and shaping, the teeth were randomly divided into four groups of 15 teeth each and obturated with Thermafil obturators or Soft-Core obturators using Ultrafil or Trifecta low-temperature thermoplasticized gutta-percha techniques. Temperature changes on the external mesial root surfaces were measured using a thermal imaging camera. Their findings suggested that solid core gutta-percha combined with low-temperature injectable gutta-percha obturation techniques may impose less risk for thermal damage to the sur- rounding periradicular tissues.

Nadler et al (2004)[53] provided an overview of the physiologic basis and clinical applications of cryotherapy and thermotherapy for the pain

practitioner. Continuous low-level cryotherapy and thermotherapy are newer concepts in therapeutic modalities. Both modalities provided significant pain relief with a low side-effect profile. Contrast therapy, which alternates between hot and cold treatment modalities, provided no additional therapeutic benefits compared with cryotherapy or thermotherapy alone. Complications of cryotherapy include nerve damage, frostbite, Raynaud's phenomenon, cold-induced urticaria, and slowed wound healing. With thermotherapy, skin burns may occur, especially in patients with diabetes mellitus, multiple sclerosis, poor circulation, and spinal cord injuries. In individuals with rheumatoid arthritis, deep-heating modalities should be used with caution because increased inflammation may occur.

Hubbard TJ et al (2004)[32] assessed whether cryotherapy improve outcomes with soft tissue injury. They concluded that cryotherapy seems to be effective in decreasing pain. Many more high-quality studies are required to create evidence-based guidelines on the use of cryotherapy. These must focus on developing modes, durations, and frequencies of ice application that will optimize outcomes after injury.

Laureano Filho JR et al (2005)[38] conducted a study to evaluate the effectiveness of cryotherapy, the therapeutic use of cold, in reducing undesirable consequences after surgery. The authors extracted two impacted mandibular third molars at different times from each patient. Immediately after surgery, the patient underwent cryotherapy on one side for 30 minutes

every one and one-half hours for 48 hours when he or she was awake. The patient did not receive cryotherapy on the other side. The authors compared both sides for differences in swelling, pain and trismus in each patient. They concluded that cryotherapy was effective in reducing swelling and pain in this sample. Despite playing no role in the reduction of trismus, cryotherapy was effective in reducing swelling and pain in this sample, and the authors still recommend it be used.

Huttala Andrew S et al (2006)[33] measured root surface temperature changes when ultrasonic vibration, with and without irrigation, was applied to cemented endodontic posts. 26 single root premolars were divided in to 2 groups. Root lengths were standardized, canals instrumented, obturated, and posts cemented into prepared spaces. Thermocouples were positioned at two locations on the proximal root surfaces. Posts were ultrasonically vibrated for 4 minutes while continuously measuring temperature. Root surface temperatures were significantly higher when posts were instrumented dry. They concluded that irrigation during post removal with ultrasonics had a significant impact on the temperature measured at the external root surface.

Koc M et al (2006)[37] evaluated whether cold therapy, applied by means of ice packs, following inguinal hernia surgery, controlled pain postoperatively. They concluded that local cooling is a safe and effective technique for providing analgesia following inguinal hernia repair.

Muldoon J (2006)[52] discussed the effects of two factors--skin cooling and pain--on chronic wound healing, and the role of pain and inflammation on the overall wound healing process.

Nielsen Benjamin A. et al (2007)[55] compared the efficacy of the EndoVac irrigation system and needle irrigation to debride root canals at 1 and 3 mm from working length. One tooth was instrumented and irrigated by using the EndoVac while the other tooth was instrumented and irrigated with a 30-gauge ProRinse irrigating needle. All teeth were irrigated with sodium hypochlorite (NaOCl) and ethylenediaminetetraacetic acid (EDTA) for a predetermined amount of time, and total volume of irrigant used was recorded. At the 1-mm level, significantly less debris was found in the EndoVac group. At the 3-mm level, there was no significant difference between groups. Significantly more irrigant was delivered with the EndoVac. The study showed significantly better debridement at 1 mm from working length by using the EndoVac compared with needle irrigation.

Algafly Amin A. et al (2007)[3] conducted a study to determine the impact of the application of cryotherapy on nerve conduction velocity (NCV), pain threshold (PTH) and pain tolerance (PTO). They concluded that cryotherapy can increase PTH and PTO at the ankle and this was associated with a significant decrease in NCV. Reduced NCV at the ankle may be a mechanism by which cryotherapy achieves its clinical goals.

Horan Brooks B. et al (2008)[31] measured the root surface temperature changes on thin-rooted and thick-rooted teeth undergoing ultrasonic vibration of cemented posts, with and without irrigation. Twenty-four single canal teeth were decoronated, length standardized, instrumented, obturated, and cemented with prefabricated posts. The teeth were divided into thin-rooted or thick-rooted groups. Thermocouples were cemented to the external proximal root surfaces adjacent the post ends. The roots were then mounted in standardized plaster molds and placed in a temperature-controlled water bath. Posts were ultrasonically vibrated with and without irrigation, and external root temperatures were recorded from an initial 37°C baseline for a period of 4 minutes. They concluded that no significant differences were found in temperature change between the thin-rooted and thick- rooted groups, with or without irrigation. Correlation analysis revealed no relationship between dentin thickness and temperature change

Sathorn C et al (2008)[72] assessed the evidence regarding postoperative pain and flare-up of single- or multiple-visit root canal treatment. The results showed that the prevalence of postoperative pain ranged from 3% to 58%. The heterogeneity amongst included studies was far too great to conduct meta-analysis and yield meaningful results.

Risso PA et al (2008)[66] evaluated the frequency and intensity of postobturation pain and associated factors in adolescents undergoing one and two-visit root canal treatment. They concluded that postobturation pain was

more present in the two-visit group, but was not statistically significant. The intensity of postobturation pain was similar. Effective microbiological control and the presence of preoperative pain may influence the postobturation pain in adolescents.

Attar S (2008)[11] compared single-dose ibuprofen pretreatment for postoperative endodontic pain. Thirty-nine patients were randomly assigned to 3 groups: placebo, ibuprofen tablets, or ibuprofen liquigels. Patients recorded their pain levels before and at the end of treatment, then every 6 hours for 24 hours after administration of the medications and standard endodontic treatment. The results showed no significant differences in postoperative pain levels between single-dose ibuprofen formulation or the placebo control group. Patients treated with calcium hydroxide versus obturation did not differ in postoperative pain levels. They concluded that single-dose pretreatment analgesia alone will not significantly reduce postoperative pain following endodontic treatment.

Pochapski MT (2009)[64] evaluated the use of a preoperative single oral dose of dexamethasone for the prevention and control of postendodontic pain. They concluded that preoperative single oral dose of dexamethasone substantially reduced postendodontic pain. Further studies are needed to evaluate the applicability of these findings to other clinical conditions and drug regimens.

Lipski Mariusz et al (2010)[41] in the invitro study evaluated the temperature changes on the root surface of teeth during preparation of post space with and without water cooling. After root canal obturation in 30 extracted premolars, the teeth were divided into 2 groups, and post spaces were prepared by using a drill without cooling (dry group) and with water irrigation of 25 mL/min (wet group). They concluded that irrigation during post space preparation significantly influenced the outer root surface temperature. The risk of irreversible injury to the root surrounding tissues is potentially minimized when post space is prepared by using water cooling.

Siu Chris et al (2010)[75] compared the debridement efficacy of EndoVac irrigation versus conventional needle irrigation *in vivo*. The samples were divided into 2 groups- Endovac irrigaton group and conventional needle irrigation group. EndoVac irrigation resulted in significantly less debris at 1 mm from WL compared with conventional needle irrigation. There was no significant difference at the 3-mm level.

Parente JM et al (2010)[58] examined canal debridement efficacy by testing the null hypothesis that there is no difference between a 'Closed' and an 'Open' system design in smear layer and debris removal using either manual dynamic agitation or the EndoVac for irrigant delivery. They concluded that the presence of a sealed apical foramen adversely affected debridement efficacy when using manual dynamic agitation but not the

EndoVac. Apical negative pressure irrigation is an effective method to overcome the fluid dynamics challenges inherent in closed canal systems.

Wang C et al (2010)[83] compared the incidence and intensity of postobturation pain after one or two-visit root canal treatment (RCT) on anterior teeth with vital pulps and a single root and canal in a randomized controlled trial. They concluded that incidence and intensity of post obturation pain experience following one or two-visit RCT on teeth with vital pulps and a single canal were not significantly different.

Alves Vde Oliviera et al (2010)[9] evaluated the incidence of flare-ups and identified the risk factors associated with their occurrence in patients who received endodontic treatment for a year at the endodontics clinic of the São Paulo Dental Association (APCD), Jardim Paulista branch, São Paulo, Brazil. The incidence of flare-ups was 1.71% out of 408 teeth that had received endodontic therapy. Statistical analysis indicated a direct correlation between the flare-up rate and the presence of a periradicular radiolucency.

Lipski Mariusz et al (2010)[40] evaluated the rise in temperature on the outer root surface of human incisors during ultrasonic post removal with different water flows. After root canal preparation in 36 extracted teeth, the teeth were obturated, and prefabricated posts were cemented into the prepared spaces. Posts were ultrasonically instrumented dry and with irrigation at 20 mL/min and 40 mL/min. Temperature changes on the entire mesial outer

surfaces of the roots were measured at 10-second intervals using an infrared thermal imaging camera. Results of their study showed that the increase in root surface temperature were significantly lower when posts were instrumented with 40 mL/min water irrigation compared with dry vibration and 20 mL/min irrigation, which also significantly differed from each other. They concluded that water cooling during ultrasonic post instrumentation significantly reduced temperature increases on the outer root surface.

Pak JG et al (2011)[57] determined the influence of root canal treatment on pain prevalence and severity and estimated the prevalence and severity of pretreatment, treatment, and post treatment pain in patients receiving root canal treatment. Pretreatment root canal-associated pain prevalence was high but dropped moderately within 1 day and substantially to minimal levels in 7 days. Pretreatment root canal-associated pain severity was moderate, dropped substantially within 1 day of treatment, and continued to drop to minimal levels in 7 days. Supplemental anesthesia was often required.

Pereira Thiago Martini et al (2011)[62] measured thermal diffusivity of enamel and dentin using infrared camera. The mean result of thermal diffusivity obtained for enamel was $0.0084 \pm 0.001 cm^2/s$ for the temperature range of 220-550ºC. This value is approximately constant for the temperatures up to 550 ºC. The mean value for thermal diffusivity obtained for dentin was $0.0015 \pm 0.0004 cm^2/s$ in temperatures up to 360ºC.

George GK et al (2011)[28] evaluated the effect of deep dry cryotherapy on the cyclic fatigue resistance of rotary nickel titanium instruments. The results of their study showed a significant increase in the resistance to cyclic fatigue of deep dry cryotreated NiTi files over untreated files.

Lipski Mariusz et al (2011)[42] evaluated the temperature rise on the outer root surface of the mandibular first molar following root canal filling using the high-temperature, thermoplasticized, Gutta-Percha technique (HTTG) (BeeFill) in the dog. Twelve extracted dog mandibular first molars were used. After root canal preparation, the teeth were filled with thermoplasticized Gutta-Percha and root canal sealer. Temperature changes on the vestibular surfaces of the mesial and distal roots of mandibular first molars were measured using a thermal imaging camera. The results of this invitro study showed that using HTTG to fill mandibular first molars in dogs produces a safe temperature rise on the root surface and, therefore, should not damage the periodontal ligament and/or surrounding tissues.

Kara Tuncer Aysun et al (2012)[34] evaluated the effects of different solutions used for final irrigation on sealer penetration into dentinal tubules. They concluded that final irrigation with EDTA, Maleic Acid, and Citric Acid after the use of NaOCl affected sealer penetration. However, there was no significant difference between these experimental groups

Gotler M et al (2012)[29] evaluated the incidence and severity of postendodontic treatment pain (PEP) subsequent to root canal treatment (RCT)

in vital and necrotic pulps and after retreatment. The results showed that RCT of teeth with vital pulp induced a significantly higher incidence and intensity of PEP compared to teeth with necrotic pulp or retreated teeth.

Peeters Harry Huiz et al (2012)[61] evaluated the magnitude of temperature changes in the tooth during cavitation produced by an Er,Cr:YSGG laser at 2 W for 120 seconds in maxillary canine. The tooth was processed as follows. In the EDTA condition, the tooth was irrigated with 17% EDTA; in the NaOCl condition, the tooth was irrigated with 3% NaOCl; and to analyse the effect of different thicknesses of dentin, the tooth was irrigated with tap water. In all conditions, the irrigants were activated at 2 W for 120 seconds. They concluded that the magnitude of the temperature changes in the root canal and at the surface of the tooth did not exceed 5 ℃ when laser-driven irrigation was used to produce cavitation in the root canal.

Dina Al Sudani et al (2012)[20] evaluated and compared the incidence and intensity of postoperative pain using two different nickel-titanium instrumentation techniques: a rotary crown-down technique using TF instruments and a reciprocating single-file technique using Reciproc instruments. The results showed a statistically significant difference between the two techniques. When comparing patients who developed no pain, the TF instrumentation technique showed significantly better results. When evaluating patients experiencing severe pain, the incidence of symptoms was significantly higher with the Reciproc technique.

Parirokh M et al (2012)[59] investigated the effect of a long-acting anesthetic (bupivacaine) on postoperative pain and the use of analgesics after root canal treatment. Patients who received bupivacaine as the anesthetic agent for single-visit endodontic treatment of irreversible pulpitis in mandibular molars had significantly less early postoperative pain and used fewer analgesics than those who had lidocaine as the anesthetic.

Alonso-Ezpeleta Luis O. et al (2012)[8] investigated and compared postoperative pain after one-visit root canal treatment (RCT) on teeth with vital pulps using three different obturation techniques- cold lateral compaction of gutta-percha (LC), Thermafil technique (TT), and Backfill - Thermafil obturation technique (BT). They concluded that patients whose teeth were filled with Thermafil obturators (TT technique) showed significantly higher levels of discomfort than patients whose teeth were filled using any of the other two techniques.

De Gregorio et al (2013)[19] determined the effect of apical preparation size and preparation taper on the volume of irrigant delivered at the working length for different canal curvatures using apical negative pressure irrigation. The results showed that the degree of root canal curvature decreased the volume of irrigant at the working length for a given apical size and taper. An apical preparation of 40.06 significantly increased the volume and exchange of irrigant at the working length regardless of curvature.

Amade Euridsse Sulemane et al (2013)[10] investigated the effects of

endodontic treatment procedures and different post systems rehabilitation steps on the strain and temperature rise on apical and cervical root dentin regions. The strain and temperature rise were recorded in 20 canines during the following procedures: root canal preparation, final rinse and drying, root canal filling and canal relief. Then the teeth were divided into three groups (n=7), according to the type of post system: CPC, cast post and core; FGP, fiberglass post; and PSP, prefabricated steel post. The results showed that the post-space preparation caused the highest temperature rise (4.0-14.9 °C) and the highest strain in the apical region during irrespective of post type. The resin cement light-activation resulted in significant temperature increases in the cervical region for all of the groups. The canal relief and the post-space preparation produced highest temperature rises. The CPC post modeling resulted in higher root strain level similarly the level of post preparation. The PSP resulted in highest strain during post trying and post cementation.

Parirokh M et al (2013)[60] evaluated the effect of occlusal reduction on postoperative pain in teeth with irreversible pulpitis and tenderness to percussion. After access opening and calcium hydroxide dressing, in one group, the occlusal surface was reduced (OR group), whereas in the other group the occlusal surface was not modified (no occlusal reduction, NOR group). Each patient was asked to record their postoperative pain on a visual analogue scale with 4 categories at 6 hours, 12 hours, 18 hours, 1 day, and then daily for 6 days. They concluded that occlusal surface reduction did not

provide any further reduction in postoperative pain for teeth with irreversible pulpitis and mild tenderness to percussion compared with no occlusal reduction.

Modabber Ali et al (2013)[51] compared postoperative cooling therapy applied through the use of cooling compresses with the water-circulating cooling face mask manufactured by Hilotherm in terms of beneficial impact on postoperative facial swelling, pain, eye motility, diplopia, neurological complaints and patient satisfaction. They concluded that patients receiving a cooling therapy by Hilotherm demonstrated significantly less facial swelling, less pain, reduced limitation of eye motility and diplopia, fewer neurological complaints and were more satisfied compared to patients receiving conventional cooling therapy.

Macedo RG et al (2014)[45] conducted a study to monitor temperature changes inside the root canal and test the influence of different external temperatures, flow rate, duration of irrigation and apical patency on the evolution of the temperature of injected pre-heated irrigant and the time that it remains above 45°C, and to introduce and validate a numerical model to study the thermodynamics of root canal irrigants. The results showed that once the irrigation is stopped, the temperature dropped rapidly. The experimental model showed that the dentinal wall thickness and the periradicular tissue affect the temperature at the external surface of the tooth, but have limited effect on the irrigant temperature inside the root canal.

Watkins AA (2014)[84] evaluated whether patients who received cryotherapy would report lower pain scores as a primary outcomes measure. They concluded that ice packs are a simple, cost-effective adjuvant for decreasing postoperative pain and narcotic use in patients undergoing major abdominal operations.

Zhang Jianying et al (2014)[86] hypothesized that the beneficial effects of cryotherapy in tendons are mediated by downregulation of PGE2 levels. To test this hypothesis, they applied cold treatment to mouse patellar and Achilles tendons using two animal models: exhaustive mouse treadmill running and acute mouse tendon injury by needle penetration. They then measured the levels of PGE2 and protein expression levels of COX-2, an enzyme responsible for PGE2 production in tissues, under both experimental conditions. They found that treadmill running increased PGE2 levels in both patellar and achilles tendons compared to control mice without running. Cold treatment for 30 min after treadmill running was sufficient to reduce PGE2 levels to near baseline control levels in both tendons. An extension of cold treatment to 60 min resulted only in a marginal decrease in patellar tendons, but a marked decrease in Achilles tendons. COX-2 protein levels in both tendons were also lowered by cold treatment, suggesting that the reduction of PGE2 levels in tendons by cold treatment is at least in part due to the decreased COX-2 expression. The results of this study suggest that the ability

of cold treatment to reduce pain may be attributable to its ability to decrease PGE2 production in tendons.

Uzunov T et al (2014)[80] conducted a survey to register the thermal changes that occured on the tooth surfaces during laser treatment of the root canal in an invitro study in 30 extracted teeth. Teeth were prepared with ProTaper nickel-titanium machine tools and wiped dry. During the course of laser treatment of root canals with a diode laser DenLase, temperatures changes on the surface of the hard dental tissues were recorded with infrared camera FLIR T330. They processed the captured thermal images with software product Flir Reporter Pro 9. They concluded that, temperature changes in hard dental tissues at diode laser treatment of the root canal are biocompatible.

Vera Jorge et al (2015)[81] validated a new methodology to reduce and maintain external root surface temperature for at least 4 minutes. Twenty extracted single-rooted teeth were instrumented to size 35/.06 and subjected to 2 different irrigation interventions with a repeated-measures design using 5% sodium hypochlorite first (control) and 2.5 C cold saline solution later (experimental) with EndoVac system (Kerr Endo, Orange County, CA) inserted to the working length. The initial and lowest temperatures were recorded in the apical 4 mm with a digital thermometer for both irrigants. They concluded that using cold saline solution as the final irrigant reduced the external root surface temperature more than 10 C and maintained it for 4

minutes, which may be enough to produce a local anti-inflammatory effect in the periradicular tissues

Mathew Shibu Thomas (2015)[47] analyzed the effect of certain factors like, gender, teeth type, single/multiple visits, and pre-obturation pain, on the incidence of post endodontic pain. Electronic database were searched in a systematic method according to the preferred reporting items for systematic review and meta analysis guidelines, with specified inclusion criteria to identify randomized clinical trials and exclude case reports and expert case series. He stated that the variables that affected post endodontic pain can be classified into gender, type of teeth, relation with pre-obturation pain, single/multiple visits, medications, instrumentation and obturation techniques and vitality of teeth. The author suggested that the factors that influenced the post endodontic pain were interrelated and directly interdependent.

Dua Ankur et al (2015)[21] compared the efficacy of EndoVac irrigation system and side-vented closed ended needle (Max-I probe) in removing smear layer from root canals at 1 mm and 3 mm from working length using ProTaper rotary instrumentation. The results showed that at 3 mm level, there was no significant difference between two groups and at 1 mm level, EndoVac group showed significantly better smear layer removal compared with Max-I probe. They concluded that EndoVac system results in better smear layer removal at 1 mm from working length when compared to Max-I probe irrigation

Ozcocak I et al (2015)[56] evaluated changes in temperature on the external root surface during endodontic treatment with different rotary systems. 50 extracted mandibular incisors were divided into 3 groups- Group 1: The OneShape Endodontic File no.: 25; Group 2: Reciproc Endodontic File no.: 25; Group 3: The WaveOne Endodontic File no.: 25. During the preparation, the temperature changes were measured in the middle third of the roots using a noncontact infrared thermometer. The results showed that increase in temperature caused by the OneShape file system were lower than those of the other files . The WaveOne file showed the highest temperature increase.

Chauhan Anilkumar et al (2015)[17] investigated the influence of temperature rise on a single rooted tooth during biomechanical tooth preparation, obturation and root canal preparation for radicular post. 45 extracted human mandibular premolars were randomly divided into 5 groups of 9 teeth each after access cavity preparation. In group 1 and group 2, cleaning and shaping of the root canal was done using protaper fie system and Hyflex system respectively. In group 3 and 4 obturation was done using Step-One obturation system and Calamus Dual respectively. In group 5 post space preparation was done using peeso reamers. They concluded that maximum rise in temperature was during obturation using Calamus dual (Group 4)

Freire Bruno et al (2016)[25] provided a systematic review to analyze the cryotherapy effects on circulatory, metabolic, inflammatory and neural parameters. They concluded that cryotherapy promotes a significant decrease

in blood low, in venous capillary pressure, oxygen saturation and hemoglobin (only for superficial tissues) and nerve conduction velocity. However, the effect of cryotherapy on the concentration of inflammatory substances induced by exercise, as the creatine kinase enzyme and myoglobin, was unclear.

Al-Nahlawi Talal et al (2016)[6] evaluated the effect of intracanal cryotherapy with negative pressure irrigation (EndoVac) on postendodontic pain after vital single-visit root canal treatment. Teeth were divided randomly into three groups (n = 25) according to additional irrigation protocol as follows: Group I: No additional irrigation was applied (control); group II: A 20 mL of room temperature saline was irrigated during 5 minutes using EndoVac, and group III: A 20 mL of 2 to 4°C cold saline was irrigated during 5 minutes using EndoVac. Pain levels were assessed by visual analog scale (VAS) and verbal evaluation of pain questionnaire after 6, 12, 24, 48 hours, and 7 days of canal obturation. The results showed that pain levels were high in groups I and II after 6 hours that decreased with time to almost diminish after 1 week, and on the other hand, group III showed no pain among different monitoring periods. Also pain levels in groups II were lower compared with group I after only 6 hours. They concluded that postendodontic pain presented with highest values after 6 hours of treatment and reduced to almost nil after 1 week. Intracanal cryotherapy eliminated postendodontic pain clinically and negative pressure reduced postendodontic pain after 6 hours of treatment.

Keskin Cangul et al (2016)[35] evaluated the effect of 2.5°C cold saline irrigation as final irrigant on postoperative pain after single visit root canal treatment of teeth with vital pulps. Teeth were randomly divided into two groups. In the cryotherapy group, final irrigation with 2.5°C 0.9% physiological saline solution for 5 min was performed following completion of biomechanical preparation, whereas in control group same solution stored at the root temperature was used. Treatments were performed in a single visit. Participants were asked to rate the intensity of their postoperative pain using visual analogue scale at 24 and 48 h. They concluded that 2.5°C cold saline irrigation as final irrigant can result a significant reduction in postoperative pain levels in comparison to the control group.

Ali A et al (2016)[4], investigated the correlation between the intensity of preoperative pain and the presence of postoperative pain, taking into account the variables sex, tooth type, arch, and tooth vitality. A structured questionnaire was used to record data on sex, age, type of tooth, location and pulp diagnosis. The preoperative and post operative pain levels were recorded on visual analogue scale The results showed that the mean level of pain after root canal treatment was 2.58±2.80 on a VAS between 0 and 10. Variables that were associated with a higher preoperative pain intensity (female, mandible and molar) also had a higher value of postoperative pain.

Balasubramanian Saravana Karthikeyan et al (2017)[12] provided an overview of the role of cryotherapy in post operative pain following root canal

treatment. They concluded that intracanal cryotherapy can be considered as a simple and cost-effective treatment for postoperative pain control. However, numerous research studies should be conducted in the near future to investigate the possible benefits of this technique in the treatment of other pulpal and periradicular diseases.

Materials and Methods

MATERIALS AND METHODS

ARMAMENTARIUM USED- MATERIALS

INVITRO STUDY

1. 20 extracted mandibular premolar teeth
2. Airotor highspeed handpiece [NSK, Japan].
3. Round Diamond burs [Mani Inc Japan].
4. K files 15# - 40# 21mm [Mani Inc, Japan].
5. Protaper next rotary files [Densply Maillefer, Germany].
6. NSK Endomotor [Densply Maillefer, Germany]
7. 2 ml disposable Syringes [Hindustan syringes& Medical Services Ltd].
8. Saline [Prime Dental Products PVT, India]
9. Endovac Irrigation System (Sybron Endo, Canada)
10. Digital thermometer
11. Roh thermocouple
12. Addition silicone impression material (3M ESPE)
13. Rubber dam kit (GDC, Germany)
14. Frozen bag cooler (EZ life)

INVIVO STUDY

15. 40 mandibular premolar teeth with acute irreversible pulpitis
16. Airotor highspeed handpiece [NSK, Japan].
17. Round Diamond burs [Mani Inc Japan].
18. K files 15# - 40# 21mm [Mani Inc, Japan].
19. Root ZX Apex locator mini [J morita]
20. Protaper next rotary files [Densply Maillefer, Germany].
21. X- Smart Plus Endomotor [Densply Maillefer, Germany]
22. 2 ml disposable Syringes [Hindustan syringes& Medical Services Ltd].
23. 17% EDTA solution [Prevest DenPro].
24. Sodium hypochlorite 3% [Prime Dental Products PVT, India].
25. Saline [Prime Dental Products PVT, India]
26. Endovac irrigation system [sybron endo, Canada]
27. Rubber dam kit [GDC, Germany]
28. Frozen bag cooler [EZ life]
29. Glass slab and cement spatula
30. Paper points [0.02%, DiaDent, Korea]
31. Glass ionomer cement[GC Type IX, America]
32. Gutta percha points [6%, Diadent, Korea]
33. Light cure Composite resin [Ivoclar Vivadent]

METHODOLOGY

INVITRO STUDY TO EVALUATE TEMPERATURE CHANGE

20 freshly extracted human mandibular premolars (figure 1) with single root and root canal were selected for the invitro study. Teeth with incomplete apices, decay, fractures, fissures, abnormal anatomy, or previous endodontic treatment were discarded. Access was gained with a size 4 round bur using an air turbine handpiece under copious water cooling(figure 2). A size 10 K file was inserted into the root canal to determine the working length with the help of radiographs. Working length was confirmed with electronic apex locator(figure 3). All the samples were instrumented upto the working length with Protaper Next X3 30/0.06 (figure 3). Few drops of 3% NaOCl was used to irrigate the root canal after each instrument (figure 2). A final rinse with 17 % EDTA was used to irrigate all root canals for 1 minute and then dried with sterile paper points(figure 2). Irrigation was performed using EndoVac Irrigation system(figure 4).

The EndoVac irrigation system(figure 4) is a negative pressure irrigation device which consists of a multiport adapter, master delivery tip, macrocannula and a 31-mm microcannula. The multiport adapter plugs directly to the in-office Hi Vac. The master delivery tip which fits to the multiport adapter, provides a constant flow of irrigant without the risk of overflow. The macrocannula (figure 5) of the EndoVac system is used for removal of coarse debris inside the root canal especially in the coronal and

middle third. The MicroCannula (figure 5) is a 28 gauge needle (0.32 mm) with 12 laser-drilled, microscopic evacuation holes, each less than 100 microns in size placed at the end of the needle. Fluid is drawn to the apical termination through these holes, creating a vortex-like cleaning of the apical third.

After cleaning and shaping, each specimen was mounted on a block to hold it in place(figure 6). The tooth was isolated with a rubber dam. Type K thermocouples RoHs compliant connected to a digital thermometer was attached to the apical 4 mm of the root surface(figure 7). A flexible Young's rubber dam frame was used to allow visibility of the root and thermocouples while irrigating.

At first, saline at room temperarure (control) was delivered at the working length with the microcannula of EndoVac system for 5 minutes(figure 8). Both the microcannula and the saline solution were used at room temperature. The initial temperature and the lowest temperature reached during the procedure were recorded. If a reduction of 10° C was maintained for at least 4 minutes, that temperature was also recorded.

This was followed by experimental irrigation with cold saline at 2.5° C. Both the saline solution and the microcannulas were kept in a refrigerator until use. The saline bottle was placed in a frozen bag containing a cooling gel (figure 9) and during usage, the cold saline was syringed and delivered into the

root canal using cold microcannulas. During usage, there was a temperature drop of the saline solution upto 1 -1.5° C over the 5 minutes irrigation period. The temeprature of the saline solution was monitored with the help of digital thermometer. (figure 10) . The initial temperature before cold saline irrigation and the lowest temperature reached during the 5 minute irrigation period were recorded. If a reduction of 10° C was maintained for at least 4 minutes, that was also recorded. Datas were tabulated and statistically analysed using SPSS software system.

INVIVO STUDY TO EVALUATE THE POST OPERATIVE PAIN FOLLOWING COLD SALINE IRRIGATION

The study protocol was approved by the clinical research ethics committee. A total of 40 patients aged between 20 and 50 years were included in the study. Patients with symptomatic irreversible pulpitis with either normal apical tissues or symptomatic apical periodontitis in mandibular premolars were included in the study(figure 11,12). Mandibular premolars with immature apices or root resorption or with more than single root canals were excluded from the study. Medically compromised patients, individuals who were pregnant, patients using medications such as analgesic or antiinflammatory drugs, patients who refused to participate in the study, patients who were allergic to local anesthesia were also excluded from the study.

A written consent (approved by the institutional review board) was obtained for the acceptance of the treatment from the patient. All patients were administered local anesthesia of 1:80,000 lidocaine with adrenaline via mental nerve block. Tooth was isolated with rubber dam(figure 11). Access was gained in the symptomatic tooth with a size 4 round bur using an air turbine handpiece under copious water cooling(figure 13). A size 10 K file was inserted into the root canal to determine the working length with the help of electronic apex locator (Root ZX, J Morita). Working length was confirmed radiographically (figure 14) .

All the samples were instrumented upto the working length with Protaper Next X3 30/0.06 (Dentsply). Few drops of 3% NaOCl was used to irrigate the root canal after each instrument. A final rinse with 17% EDTA was used to irrigate all root canals for 1 minute and then dried with sterile paper points. Irrigation was performed using EndoVac Irrigation system. The entire procedure was carried out under rubber dam isolation. Patients were randomly catergorised into 2 groups- control group (20), experimental group(20).

In the control group (20 patients), saline at room temperature was delivered at the working length with the EndoVac system for 5 minutes(figure 15). Both the microcannulas and the saline solution were used at room temperature. In the experimental group of 20 patients, the same irrigation procedure was performed, except for the use of cold saline solution at 2.5° C and cold microcannulas(figure 15). Both the saline solution and the

microcannulas were kept in a refrigerator until use.

In both groups, the root canals were dried with paper points and obturated using 6% 30 gutta-percha cones with zinc oxide eugenol as sealer(figure 16). The access cavities were restored with direct composite restorations with a base of high viscosity glass ionomer cement.

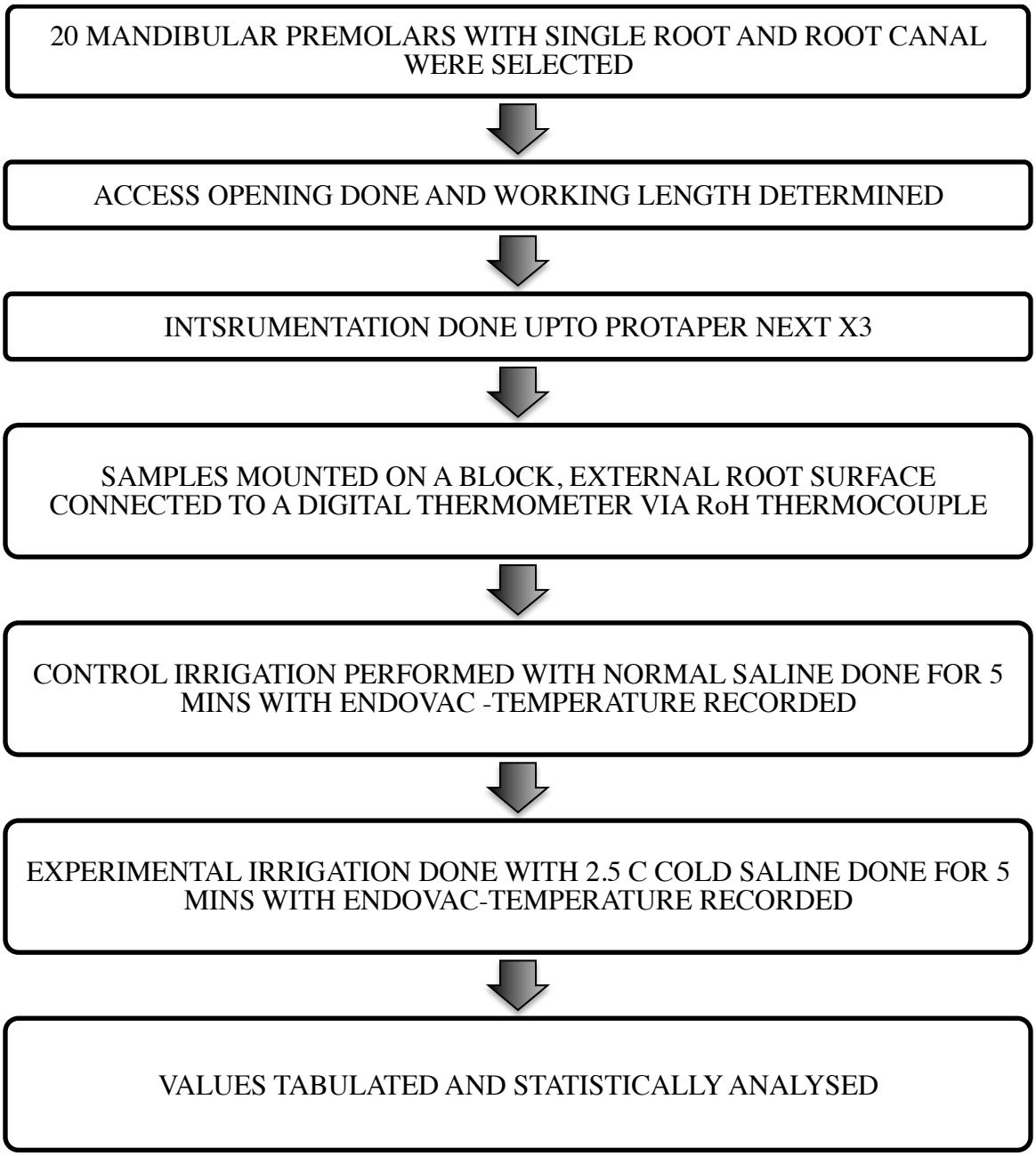
Each patient was given instruction to assess the post operative pain/ discomfort. This was carried out using a questionnaire which assessed the numeric evaluation of pain/discomfort. The questionnaire contained a 10-cm (100 mm) Heft Parker visual analog scale (VAS) to assess the degree of pain after 6, 12, 24, 48 hours , and after 4 and 7 days of canal obturation(figure 17).

The patient was asked to mark the area on the VAS that corresponds with the amount of the pain felt - 0° refers for no pain and 100° degree refers for unbearable pain. Patients were contacted on phone to remind them about registering pain according to different periods. The questionnaires were completed and received after 1 week when the patient returned for follow up. In case of severe or unbearable pain, patients were prescribed analgesics and were excluded from the study

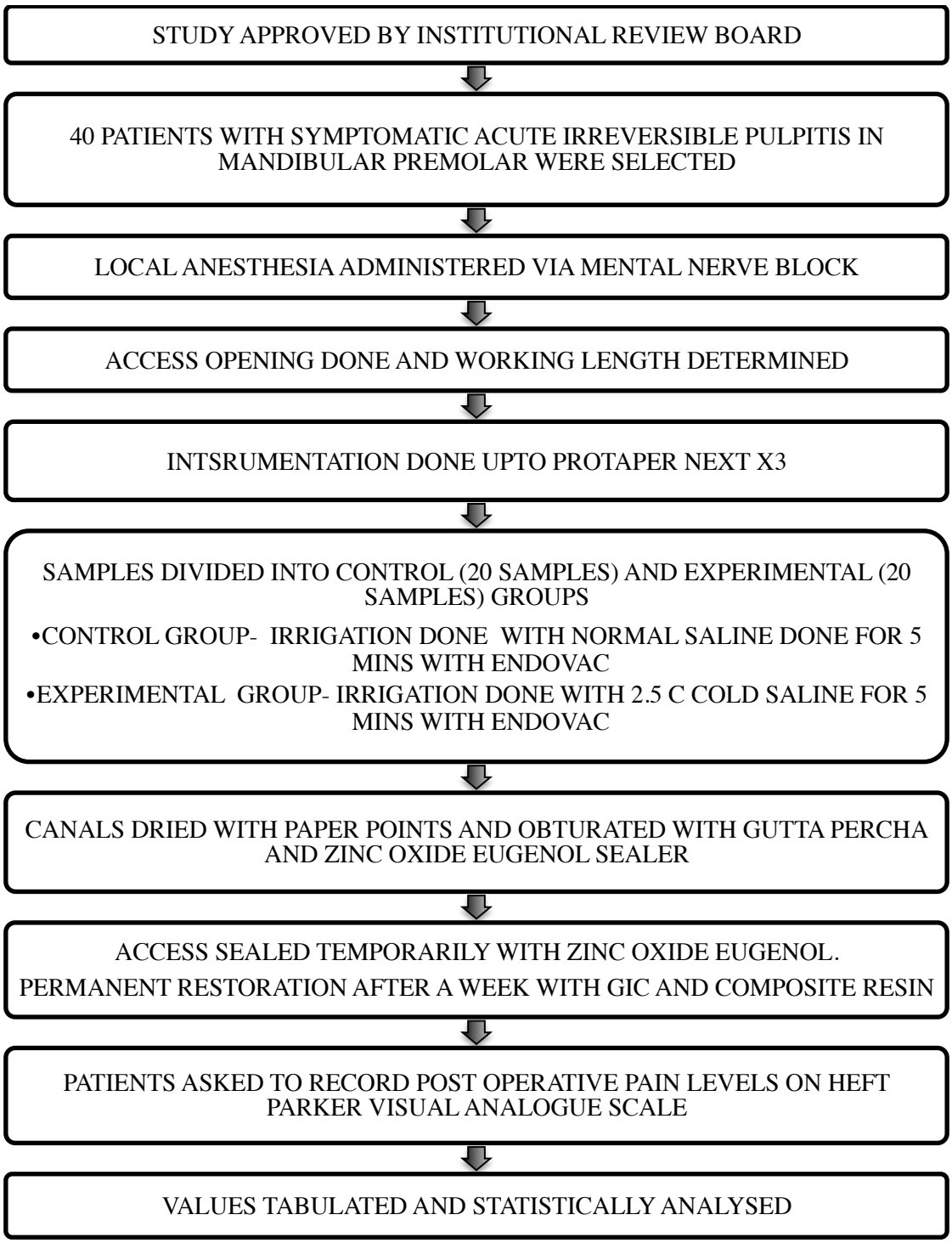
Datas were analyzed using the Statistical Package for the Social Sciences (SPSS) 13.0 computer software by using ANOVA and student t tests for comparing between the study groups.

METHODOLOGY FLOWCHART

INVITRO STUDY TO EVALUATE TEMPERATURE CHANGE ON EXTERNAL ROOT SURFACE



INVIVO STUDY TO EVALUATE THE POST OPERATIVE PAIN FOLLOWING COLD SALINE IRRIGATION



Figures

FIGURES

INVITRO STUDY TO EVALUATE TEMPERATURE CHANGE

FIGURE 1- MANDIBULAR PREMOLAR TEETH COLLECTED FOR THE INVITRO STUDY

FIGURE 2- ARMAMENTARIUM FOR ENDODONTIC TREATMENT

FIGURE 3- XSMART PLUS ENDOMOTOR (DENTSPLY) AND APEX LOCATOR(J MORITA ROOT ZX)

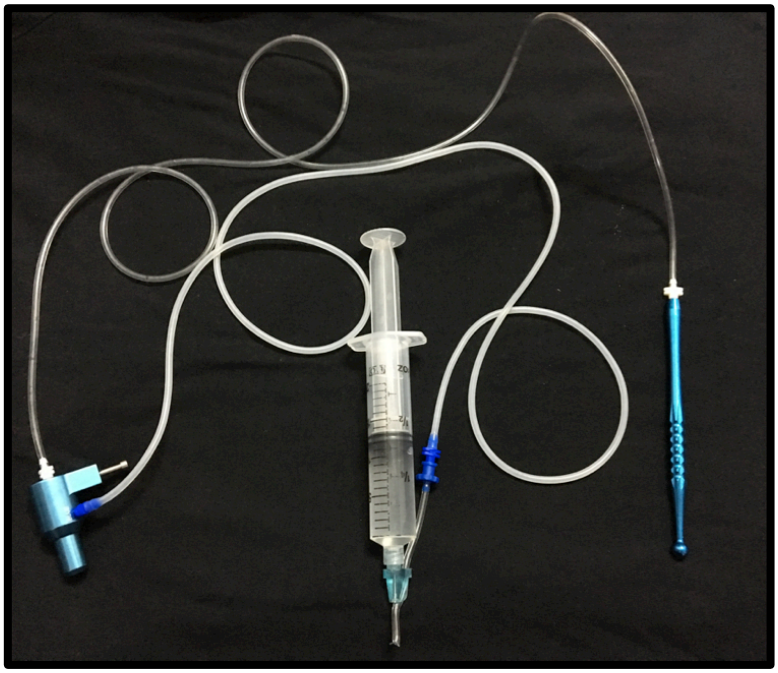


FIGURE 4- ENDOVAC IRRIGATION SYSTEM

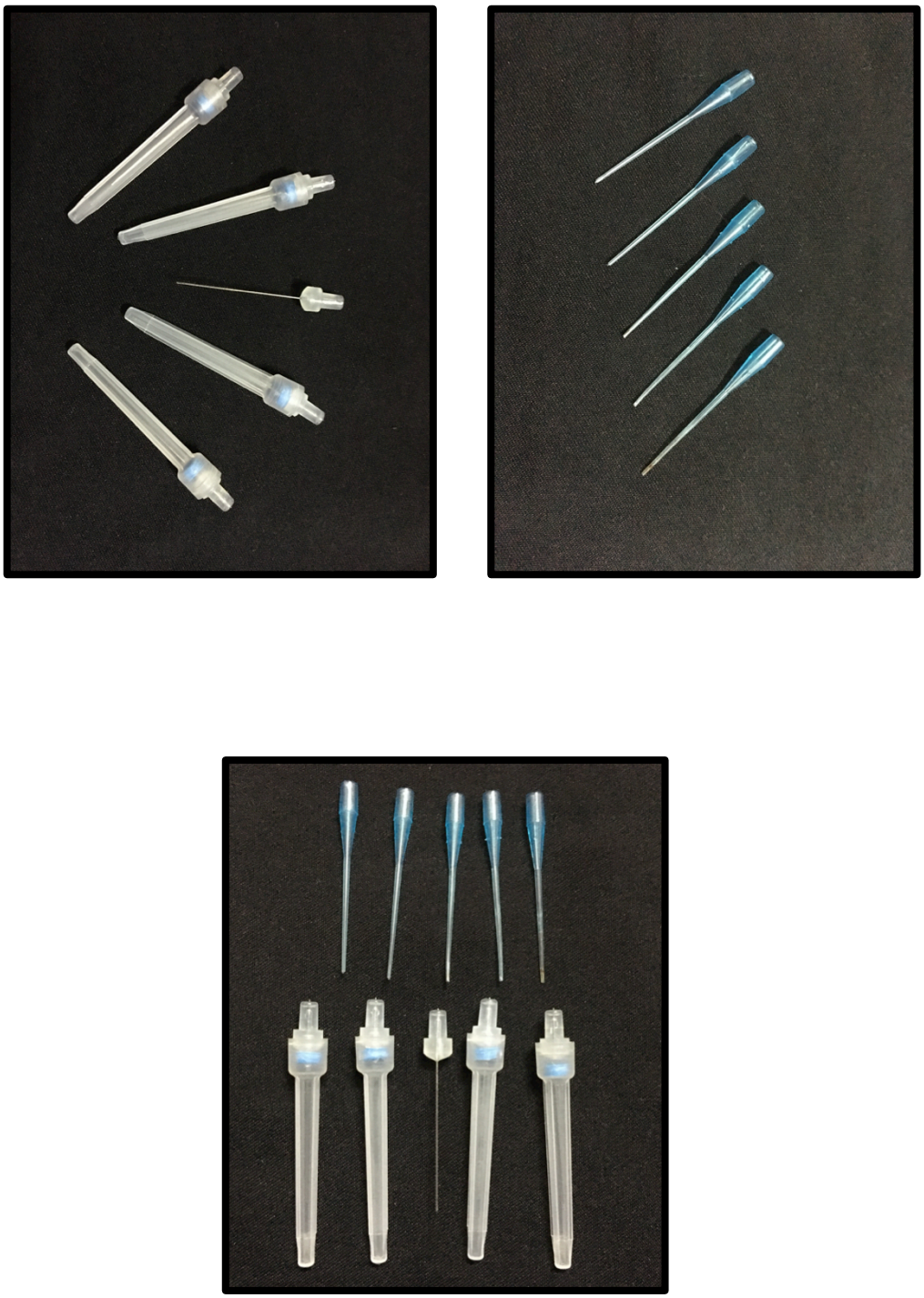


FIGURE 5-MICROCANNULAS AND MACROCANNULAS

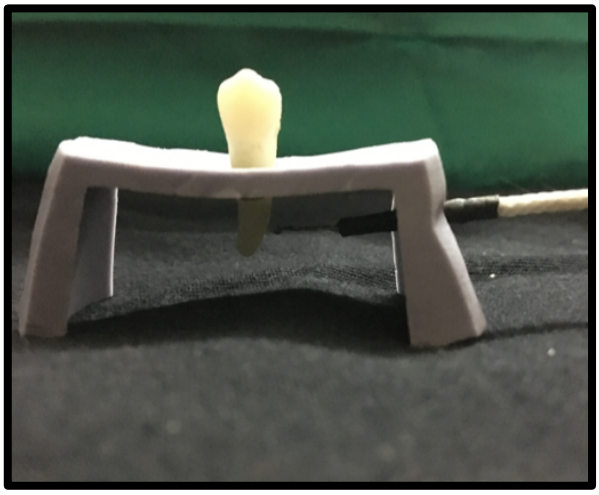


FIGURE 6- TOOTH SAMPLE MOUNTED ON A PUTTY BLOCK

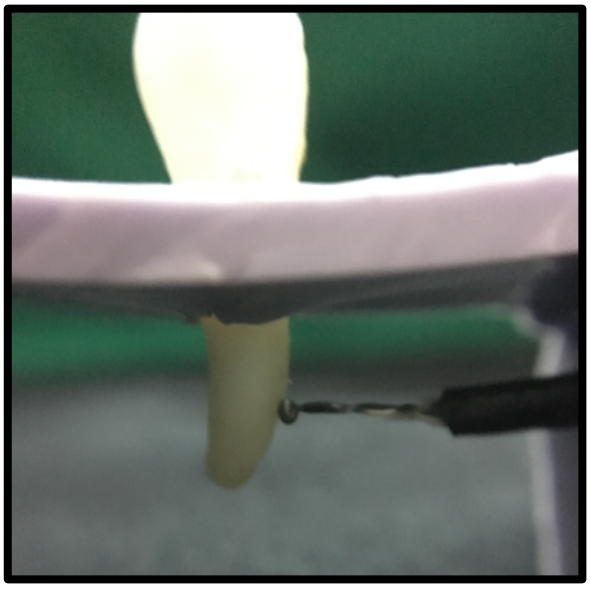
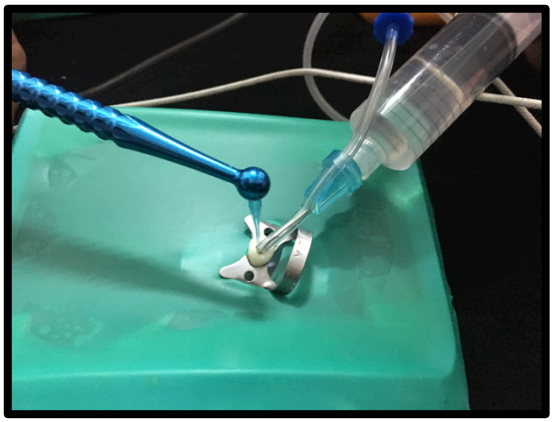
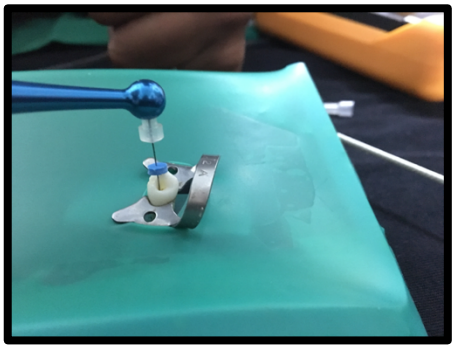


FIGURE 7- THERMOCOUPLE PLACED IN CONTACT WITH APICAL 4 MM OF ROOT SURFACE





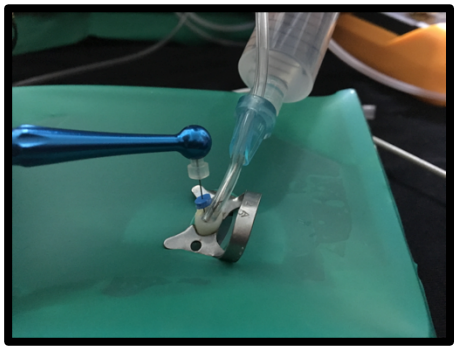


FIGURE 8- CONTROL AND EXPERIMENTAL IRRIGATIONS WITH ENDOVAC IRRIGATION SYSTEM AFTER ISOLATING WITH RUBBER DAM

FIGURE 9- SALINE BOTTLE PLACED IN THE BAG CONTAINING COOLING GEL

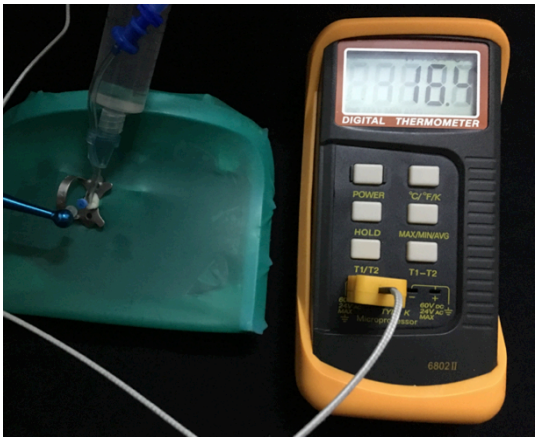


FIGURE 10- INVITRO MODEL COMPRISING OF DIGITAL THERMOMETER, RoH THERMOCOUPLE AND TOOTH SAMPLE. THE DIGITAL THERMOMETER SHOWED THE ROOT SURFACE TEMPERATURE CHANGES.

INVIVO EVALUATION OF INTENSITY OF POST OPERATIVE PAIN FOLLOWING FINAL IRRIGATION WITH COLD SALINE

FIGURE 11- TOOTH 45 FOR ROOT CANAL TREATMENT, WITH RUBBER DAM ISOLATION

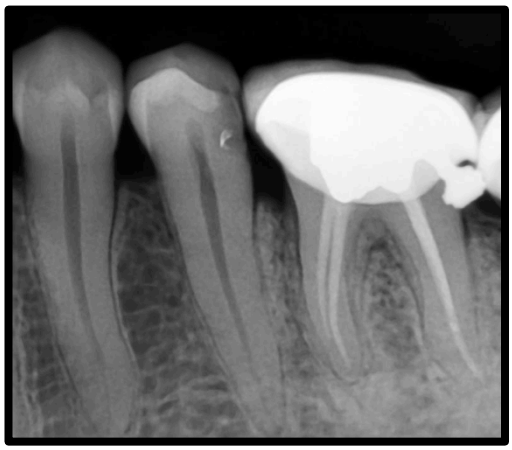


FIGURE 12- INTRA ORAL PERIAPICAL RADIOGRAPH - 45

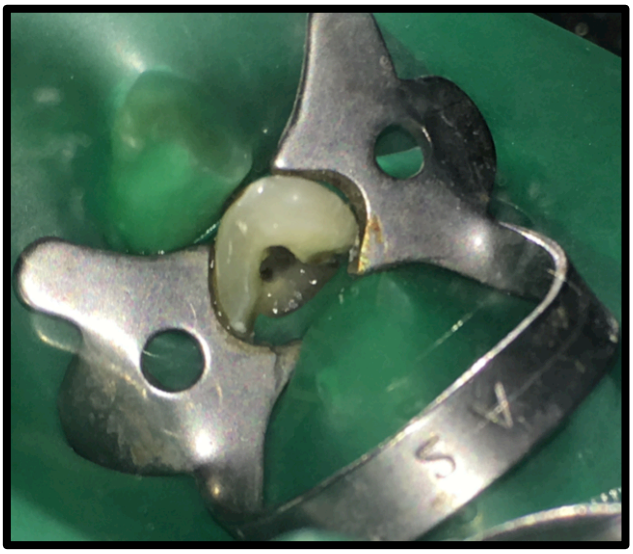


FIGURE 13- ACCESS OPENING DONE IN 45

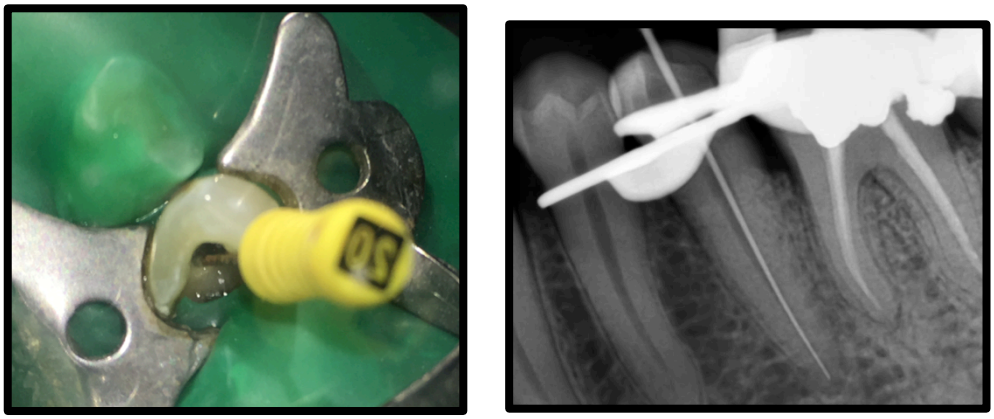


FIGURE 14- WORKING LENGTH DETERMINATION

FIGURE 15- IRRIGATION PERFORMED WITH MICROCANNULA AND MACROCANNULA OF ENDOVAC IRRIGATION SYSTEM

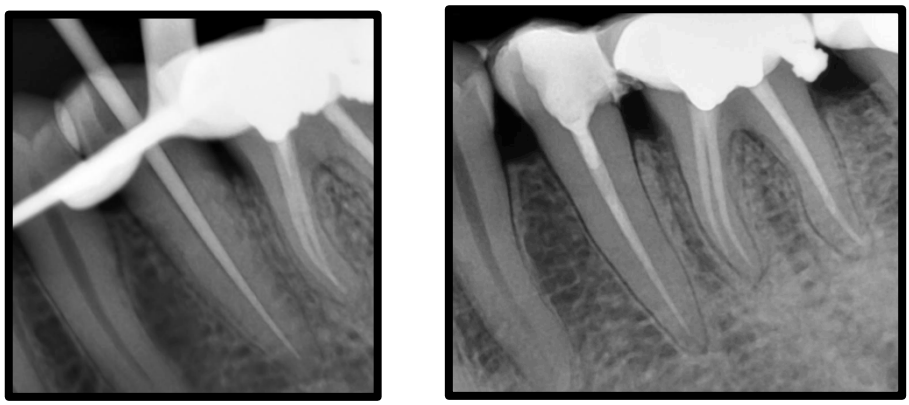


FIGURE 16- OBTURATION OF THE ROOT CANAL DONE WITH GUTTA PERCHA AND ZINC OXIDE EUGENOL SEALER

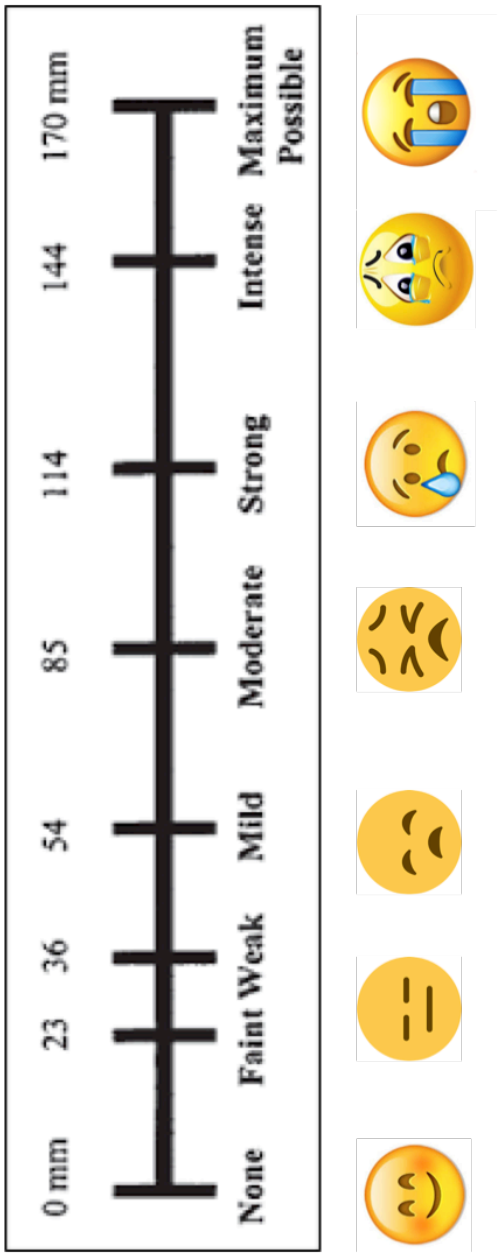


FIGURE 17- HEFT PARKER VISUAL ANALOGUE SCALE

Results

RESULTS

INVITRO EVALUATION OF TEMPERATURE REDUCTION ON EXTERNAL ROOT SURFACE.

Twenty extracted mandibular premolars were selected and single visit endodontic treatment was carried out.

Irrigation with saline at room temperature (control) for 5 mins was done with EndoVac irrigation system ,followed by the experimental irrigation with saline at 2.5 °C for 5 mins. The temperature changes on the external root surface – the initial root surface temeprature, temperature after the control irrigation, temperature following experimetal irriation (TABLE 1) was measured with the help of a digital thermometer. Datas were statistically analysed and cross tabulated using repeated measures ANOVA with Bonferroni correction.

The initial temperature recorded were 20± 2° C with a mean of 21.19 °C. Following irrigation with saline at room temperature (control), there was a maximum temperature reduction of 2° C with a mean value of 19.28° C. the lowest recorded temperature in control group after final irrigation was 18.2° C as seen in TABLE 2 AND GRAPH 1.

The experimental irrigation with cold saline solution caused a drop in the external root surface temperature within 10 seconds recording a mean

temperature of 8.69° C. The lowest recorded temperature following experimental intervention is 8.0° C.

This drop in temperature was sustained for a period of 4 mins with a change in ±0.5° C with a mean of 9.5° C. Statistically significant difference was noted among the groups.(TABLE 2)

INVIVO EVALUATION OF REDUCTION IN POST OPERATIVE PAIN FOLLOWING EXPERIMENTAL COLD SALINE IRRIGATION

40 subjects took part in the invivo study, out of which 22 patients (55%) were male and 18 (45%) were female with a mean age of 26.81 years, with the age range of 20-50 years. The participants were divided into 2 groups- control(11 male, 9 female), experimental group(11 male, 9 female). (TABLE 3)

The subjects were asked to record their immediate preoperative pain levels and then post operative pain levels at 6 hours, 12 hours ,24 hours, 48 hours, 4 days and 7 days on a Heft Parker visual analogue scale. The values were statistically analysed using Chi square test and ANOVA. TABLES 4-10 denote the scale of pain recorded by the patients at various time intervals . The pain scores were cross tabulated and were subjected to student t test to determine the significance between groups.

Preoperative pain levels among the patients tested ranged from mild in 14 patients, moderate in 12 patients and severe in 14 patients. They were

divided into 2 groups - control (mild-7, moderate-6, severe-7) and experimental group (mild-7, moderate-6, severe-7). (TABLE 11, GRAPH 2)

In the control group at 6 hours post operative, where saline at room temperature was used as the final irrigant, 8 (40%) patients experienced no pain, 7 (35%) experienced mild pain and 5 (25%) experienced moderate pain. None of the patients took analgesics for pain control. In the experimental group at 6 hours post op, where cold saline at 2.5° C was used as the final irrigant, 17 (85%) patients experienced no pain, 3 (15%) experienced mild pain. There was statistically significant differences between the groups with a p value of 0.007. (TABLE 12, GRAPH 3)

At 12 hour post operative, in control group, 8 (40%) patients had no pain, 6 (30%) experienced mild pain and 6 (30%) experienced moderate pain. One patient from the mild pain category reported a slight increase in pain which falls under moderate level. In the experimental group, 17 (85%) patients experienced no pain, 3 (15%) experienced mild pain. Significant differences in the groups were noted with a p value of 0.006.(TABLE 13, GRAPH 4)

At 24 hour post operative in control group, 8 (40%) patients experienced no pain, 7 (35%) experienced mild pain and 5 (25%) experienced moderate pain. The patient who shifted from mild to moderate pain , again dropped to mild pain level at 12 hours post op. In the experimental group,in addition to 17 patients in no pain group, one patient from mild pain reported

with no pain at 12 hour post op (90%). 2 patients (10%) reported with mild pain. The groups were statistcially significant with a p value of 0.003 (TABLE 14, GRAPH 5)

At 48 hours post operative, 9 (45%) patients experienced no pain, 8 (40%) experienced mild pain and 3 (15%) experienced moderate pain in control group. In experimental group, 19 (95%) patients had no pain and one patient (5%) had mild pain. Statistically significant difference between the groups with a p value of 0.002 was obtained.(TABLE 15, GRAPH 6)

At 4 days post operative, 14 (70%) patients had no pain and 6 (30%) patients had mild pain in control group. In the experimental group, all patients had no pain. P value of 0.020 was obtained which denotes that the groups are satistically significant.(TABLE 16, GRAPH 7)

At 7 days post operative, 18 (90%) patients had no pain and 2 (10%) patients had mild pain in control group. In the experimental group, the perception of no pain remained the same. There was no significant difference between the groups (p value-0.487) (TABLE 17, GRAPH 8)

TABLE 18 AND GRAPH 9 shows pain intensity at different time intervals in the control group. The intensity of pain reduced gradually over time. On 4^{th} day post operative, 14 patients had no pain and 6 patients had mild pain. At 7^{th} day post operative, 2 patients from mild pain reported of no pain.

TABLE 19 AND GRAPH 10 shows pain intensity at various time intervals in the experimental group. There was a significant reduction in intensity of pain. At 6 hours post operative, 17 patients reported with no pain and 3 patients had mild pain. By 4 days, all patients were free of pain.

Values were cross tabulated for different time intervals in the control and experimental groups (TABLE 18,19 AND GRAPH 9,10). It was noted that the intensity of pain was statistically significant at 6,12,24 ,48 hours post op and on 4 days. 7 days post op had no significant difference between the groups.

Tables And Graphs

TABLES

INVITRO STUDY TO EVALUATE TEMPERATURE CHANGE

TABLE 1- TEMPERATURES RECORDED ON EXTERNAL ROOT SURFACE

SAMPLE NO.	INITIAL TEMPERATURE (°C)	CONTROL GROUP (°C)	EXPERIMENTAL GROUP(°C)	10° C TEMPERATURE DROP MAINATINED UPTO 4 MINS (°C)
1	21.2	20.1	8.9	9.1
2	21.4	19.1	9.1	9.3
3	22.1	19.9	9.2	9.3
4	22.4	21.1	9.3	9.4
5	21.3	19.4	8.5	9.8
6	21.4	19.4	8.4	9.6
7	20.4	17.9	8.2	9.7
8	20.5	19.7	8	9.6
9	21	19.5	8.7	9.2
10	21.8	20.3	9.1	9.7
11	20.9	17.9	8.3	9.6
12	22.1	19.6	9.6	9.6
13	21.6	19.6	8.6	9.9
14	21.2	19.7	8.6	9.4
15	21.1	19.3	8.9	9.9
16	20.9	18.3	8.7	9.6
17	20.9	18.2	8.4	9.3
18	20.2	18.7	8.2	9.1
19	20.2	18.8	8.4	9.5
20	21.2	19.2	8.7	9.5

TABLE 2: MEAN TEMPERATURE CHANGES ASSESSED ON THE EXTERNAL ROOT SURFACE IN CONTROL AND EXPERIMENTAL GROUP

	N	MEAN (°C)
INITIAL TEMPERATURE	20	21.1900
CONTROL	20	19.2850
EXPERIMENTAL	20	8.6900
10 ° C TEMPERATURE DROP MAINTAINED UPTO 4 MINS	20	9.5050

INVIVO STUDY TO EVALUATE THE POST OPERATIVE PAIN FOLLOWING COLD SALINE IRRIGATION

TABLE 3: SAMPLE SIZE

GROUPS	NO	MALE	FEMALE
CONTROL	20	11	9
EXPERIMENTAL	20	11	9

TABLE 4: PRE OPERATIVE HEFT PARKER VISUAL ANALOGUE SCALE SCORES

PATIENT NO.	CONTROL GROUP	EXPERIMENTAL GROUP
1	24	21
2	23	23
3	26	35
4	45	43
5	35	11
6	52	12
7	26	14
8	67	59
9	76	70
10	87	67
11	89	99
12	69	78
13	109	86
14	130	120
15	143	137
16	133	140
17	154	135
18	139	158
19	154	165
20	123	134

TABLE 5: 6 HOURS POST OPERATIVE HEFT PARKER VISUAL ANALOGUE SCALE SCORES

PATIENT NO.	CONTROL	EXPERIMENTAL
1	59	0
2	76	0
3	68	0
4	95	0
5	98	11
6	50	0
7	26	0
8	35	0
9	14	0
10	24	26
11	34	0
12	19	0
13	0	0
14	0	15
15	0	0
16	0	0
17	0	0
18	0	0
19	0	0
20	0	0

TABLE 6: 12 HOURS POST OPERATIVE HEFT PARKER VISUAL ANALOGUE SCALE SCORES

PATIENT NO.	CONTROL	EXPERIMENTAL
1	57	0
2	69	0
3	63	0
4	99	0
5	98	11
6	59	0
7	26	0
8	31	0
9	14	0
10	20	24
11	34	0
12	51	0
13	0	0
14	0	13
15	0	0
16	0	0
17	0	0
18	0	0
19	0	0
20	0	0

TABLE 7: 24 HOURS POST OPERATIVE HEFT PARKER VISUAL ANALOGUE SCALE SCORES

PATIENT NO.	CONTROL	EXPERIMENTAL
1	60	0
2	74	0
3	62	0
4	92	0
5	99	14
6	53	0
7	27	0
8	34	0
9	12	0
10	26	0
11	31	0
12	32	0
13	0	0
14	0	19
15	0	0
16	0	0
17	0	0
18	0	0
19	0	0
20	0	0

TABLE 8: 48 HOURS POST OPERATIVE HEFT PARKER VISUAL ANALOGUE SCALE SCORES

PATIENT NO.	CONTROL	EXPERIMENTAL
1	60	0
2	74	0
3	62	0
4	29	0
5	38	13
6	53	0
7	27	0
8	34	0
9	12	0
10	26	0
11	31	0
12	0	0
13	0	0
14	0	0
15	0	0
16	0	0
17	0	0
18	0	0
19	0	0
20	0	0

TABLE 9: 4 DAYS POST OPERATIVE HEFT PARKER VISUAL ANALOGUE SCALE SCORE

PATIENT NO.	CONTROL	EXPERIMENTAL
1	20	0
2	14	0
3	25	0
4	29	0
5	18	0
6	23	0
7	0	0
8	0	0
9	0	0
10	0	0
11	0	0
12	0	0
13	0	0
14	0	0
15	0	0
16	0	0
17	0	0
18	0	0
19	0	0
20	0	0

TABLE 10: 7 DAYS POST OPERATIVE HEFT PARKER VISUAL ANALOGUE SCALE SCORES

PATIENT NO.	CONTROL	EXPERIMENTAL
1	12	0
2	11	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0
10	0	0
11	0	0
12	0	0
13	0	0
14	0	0
15	0	0
16	0	0
17	0	0
18	0	0
19	0	0
20	0	0

TABLE 11: HEFT PARKER VISUAL ANALOGUE SCALE ASSESSMENT - PRE OPERATIVE

GROUPS	MILD PAIN	MODERATE PAIN	SEVERE PAIN	P VALUE
CONTROL GROUP	7	6	7	**1.000**
EXPERIMENTAL GROUP	7	6	7	

TABLE 12: HEFT PARKER VISUAL ANALOGUE SCALE ASSESSMENT AT 6 HOURS POST OPERATIVE

GROUPS	NO PAIN	MILD PAIN	MODERATE PAIN	P VALUE
CONTROL GROUP	8	7	5	**.007**
EXPERIMENTAL GROUP	17	3	0	

TABLE 13: HEFT PARKER VISUAL ANALOGUE SCALE ASSESSMENT AT 12 HOURS POST OPERATIVE

GROUPS	NO PAIN	MILD PAIN	MODERATE PAIN	P VALUE
CONTROL GROUP	8	6	6	**.006**
EXPERIMENTAL GROUP	17	3	0	

TABLE 14: HEFT PARKER VISUAL ANALOGUE SCALE ASSESSMENT AT 24 HOURS POST OPERATIVE

GROUPS	NO PAIN	MILD PAIN	MODERATE PAIN	P VALUE
CONTROL GROUP	8	7	5	**.003**
EXPERIMENTAL GROUP	18	2	0	

TABLE 15: HEFT PARKER VISUAL ANALOGUE SCALE ASSESSMENT AT 48 HOURS POST OPERATIVE

GROUPS	NO PAIN	MILD PAIN	MODERATE PAIN	P VALUE
CONTROL GROUP	9	8	3	**.002**
EXPERIMENTAL GROUP	19	1	0	

TABLE 16 : HEFT PARKER VISUAL ANALOGUE SCALE ASSESSMENT AT 4 DAYS POST OPERATIVE

GROUPS	NO PAIN	MILD PAIN	P VALUE
CONTROL GROUP	14	6	**.020**
EXPERIMENTAL GROUP	20	0	

TABLE 17: HEFT PARKER VISUAL ANALOGUE SCALE ASSESSMENT AT 7 DAYS POST OPERATIVE

GROUPS	NO PAIN	MILD PAIN	P VALUE
CONTROL GROUP	18	2	**.487**
EXPERIMENTAL GROUP	20	0	

TABLE 18: CROSS TAB OF CONTROL GROUP

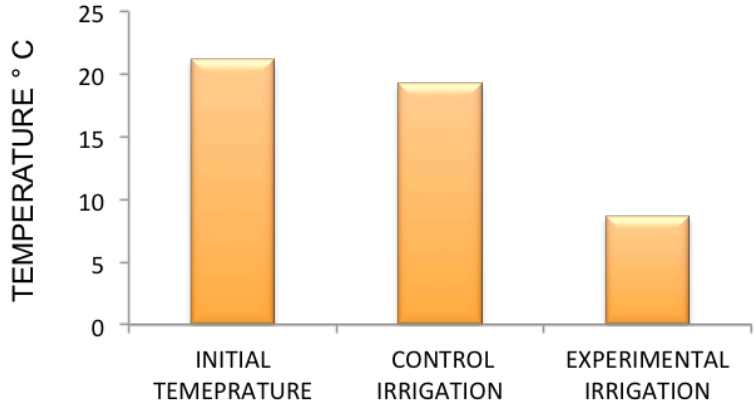
TIME PERIOD	CONTROLGROUP			
	NO PAIN	MILD PAIN	MODERATE PAIN	SEVERE PAIN
PRE OP	0	7	6	7
6 TH HR	8	7	5	0
12TH HOUR	8	6	6	0
24 HOURS	8	7	5	0
48 HOURS	9	8	3	0
4 DAYS	14	6	0	0
7TH DAY	18	2	0	0

TABLE 19: CROSS TAB OF EXPERIMENTAL GROUP

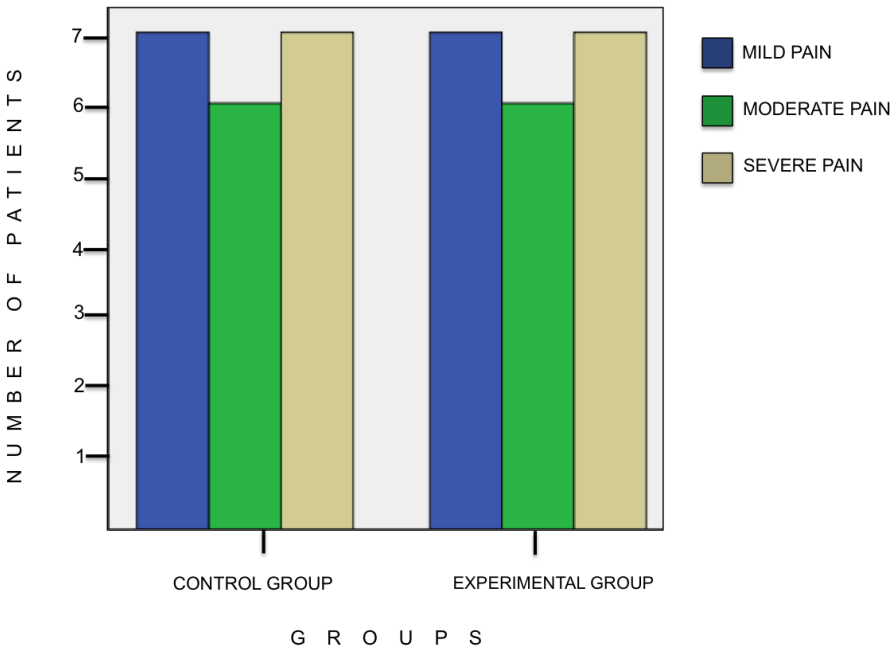
	EXPERIMENTALGROUP			
TIME PERIOD	NO PAIN	MILD PAIN	MODERATE PAIN	SEVERE PAIN
PRE OP	0	7	6	7
6 TH HOUR	17	3	0	0
12TH HOUR	17	3	0	0
24 HOURS	18	2	0	0
48 HOURS	19	1	0	0
4 DAYS	20	0	0	0
7TH DAY	20	0	0	0

GRAPHS

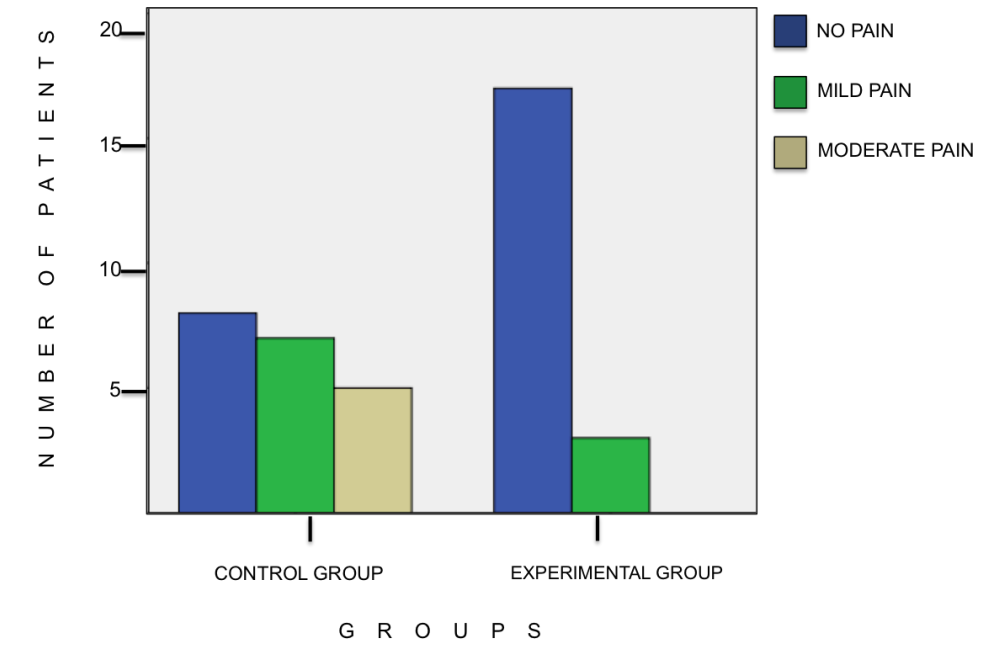
GRAPH 1: MEAN TEMPERATURE CHANGE FOLLOWING EXPERIMENTAL IRRIGATION



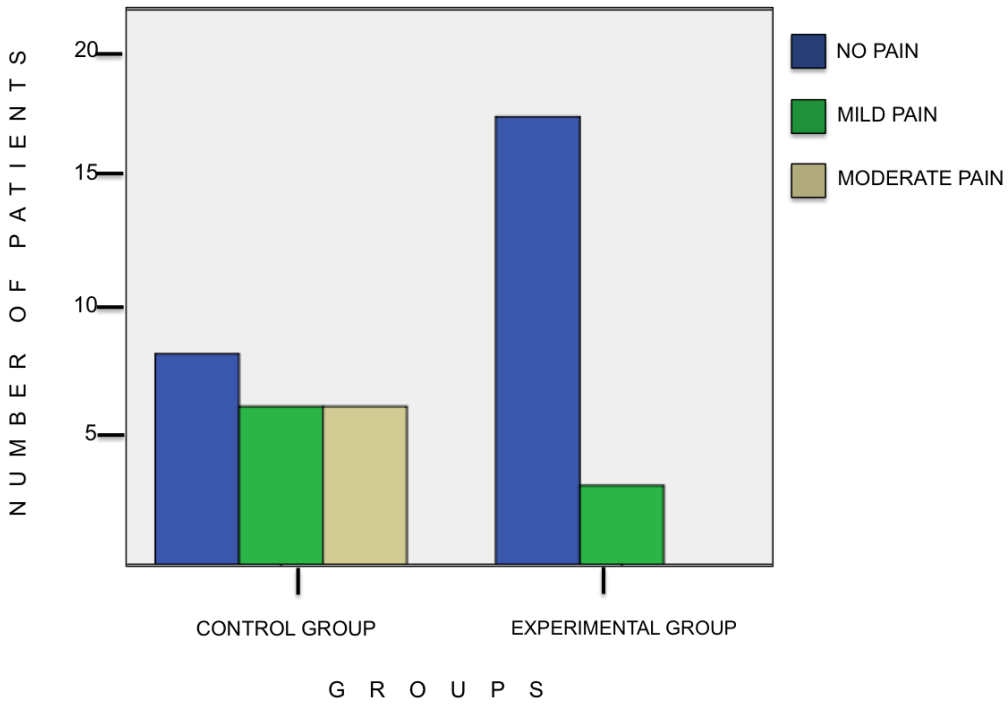
GRAPH 2: PRE OPERATIVE HEFT PARKER VISUAL ANALOGUE SCALE ASSESSMENT



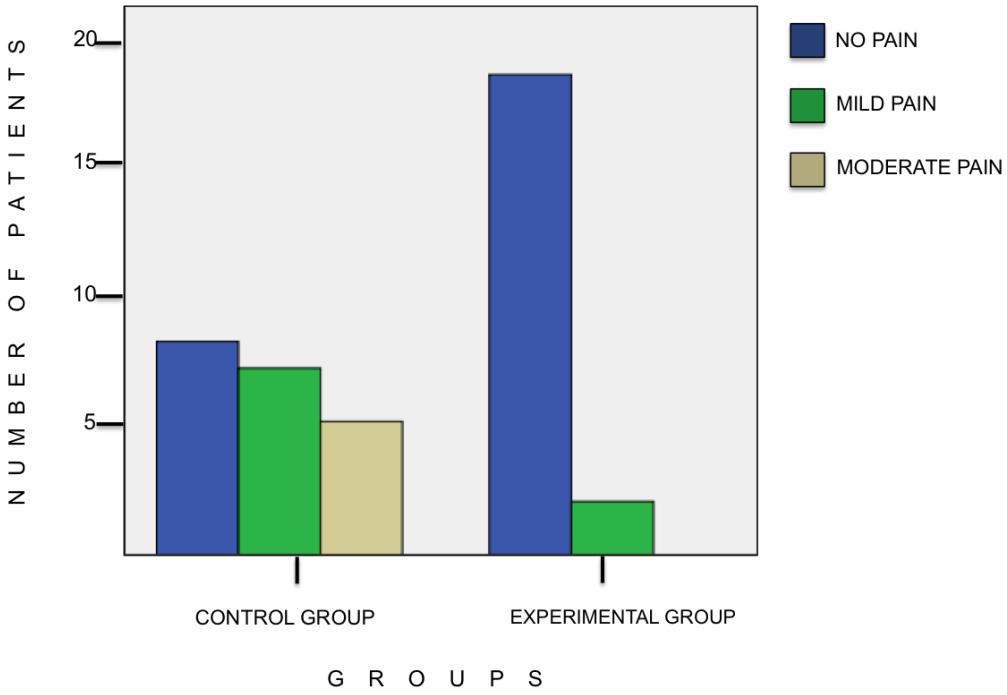
GRAPH 3: 6 HOURS POST OPERATIVE HEFT PARKER VISUAL ANALOGUE SCALE ASSESSMENT



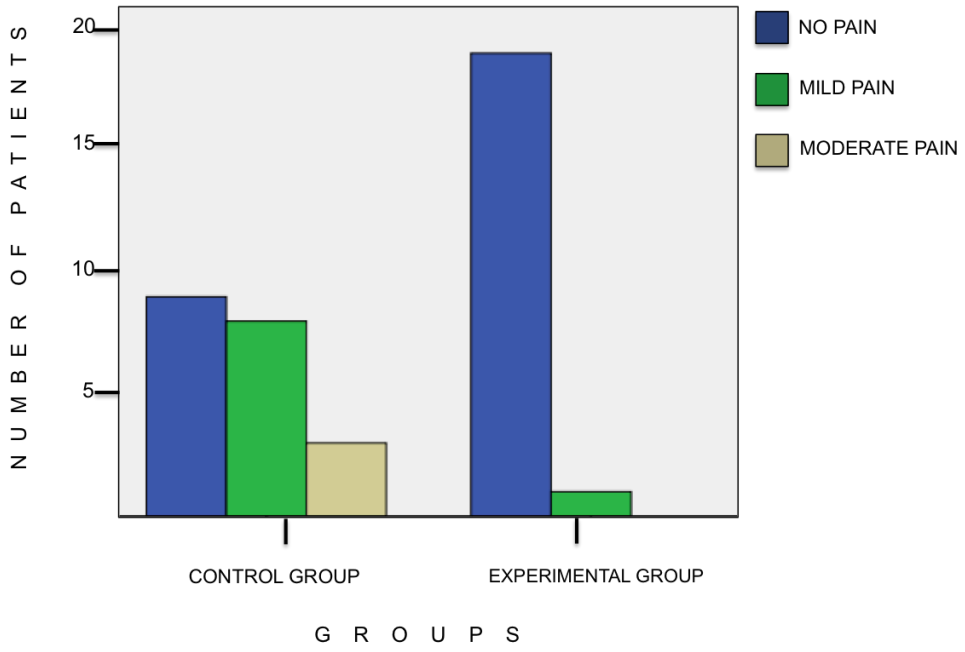
GRAPH 4: 12 HOURS POST OPERATIVE HEFT PARKER VISUAL ANALOGUE SCALE ASSESSMENT



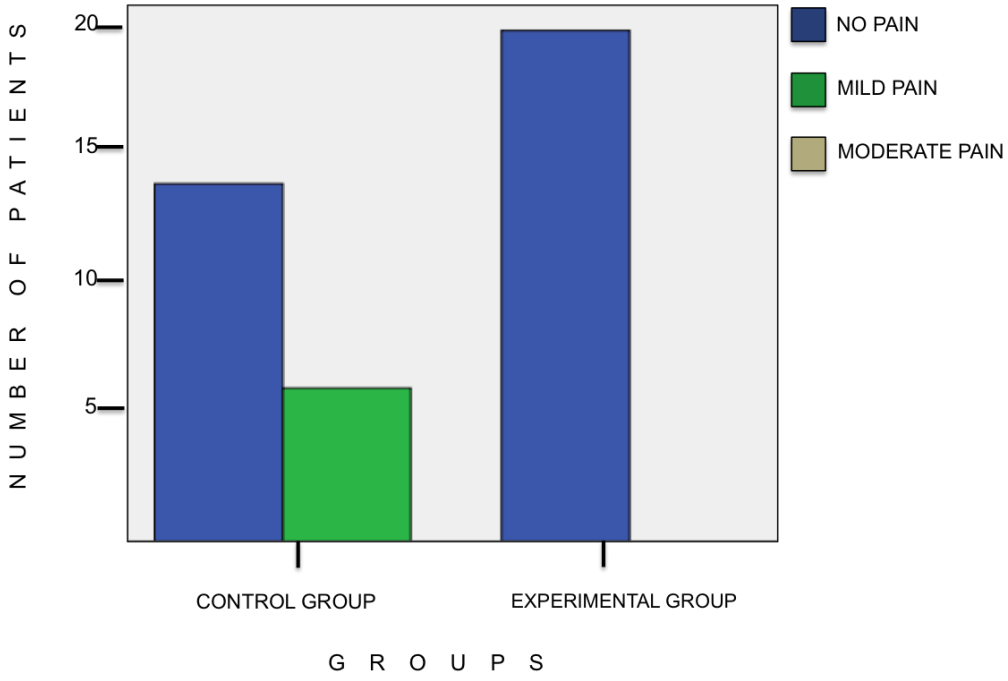
GRAPH 5: 24 HOURS POST OPERATIVE HEFT PARKER VISUAL ANALOGUE SCALE ASSESSMENT



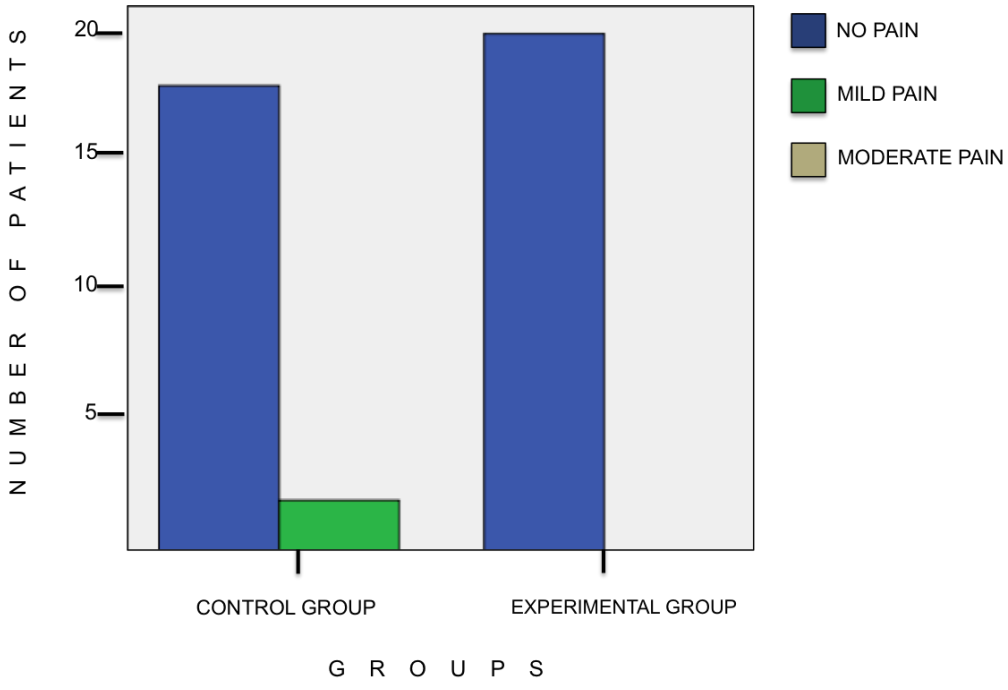
GRAPH 6: 48 HOURS POST OPERATIVE HEFT PARKER VISUAL ANALOGUE SCALE ASSESSMENT



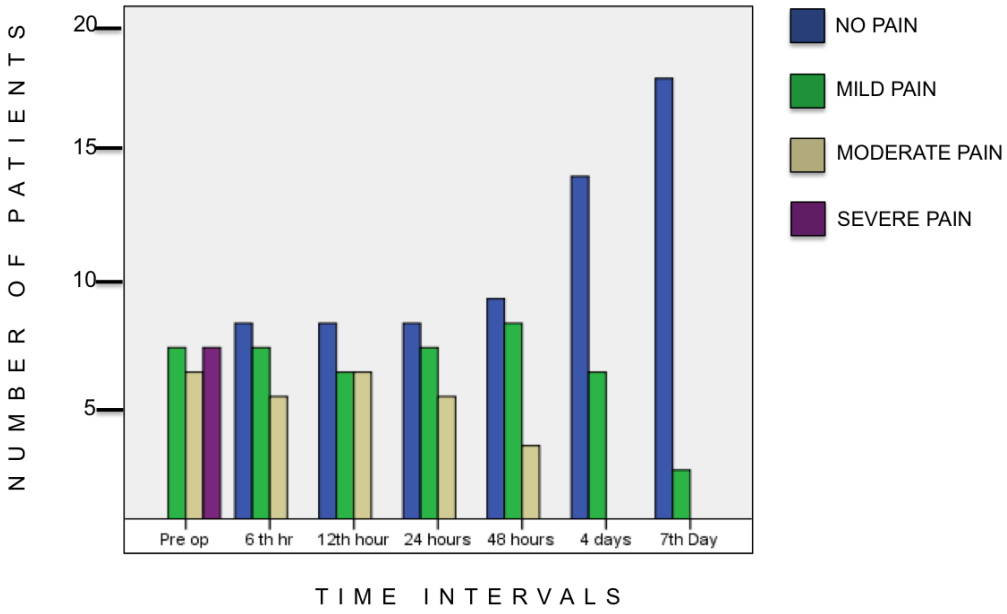
GRAPH 7: 4 DAYS POST OPERATIVE HEFT PARKER VISUAL ANALOGUE SCALE ASSESSMENT



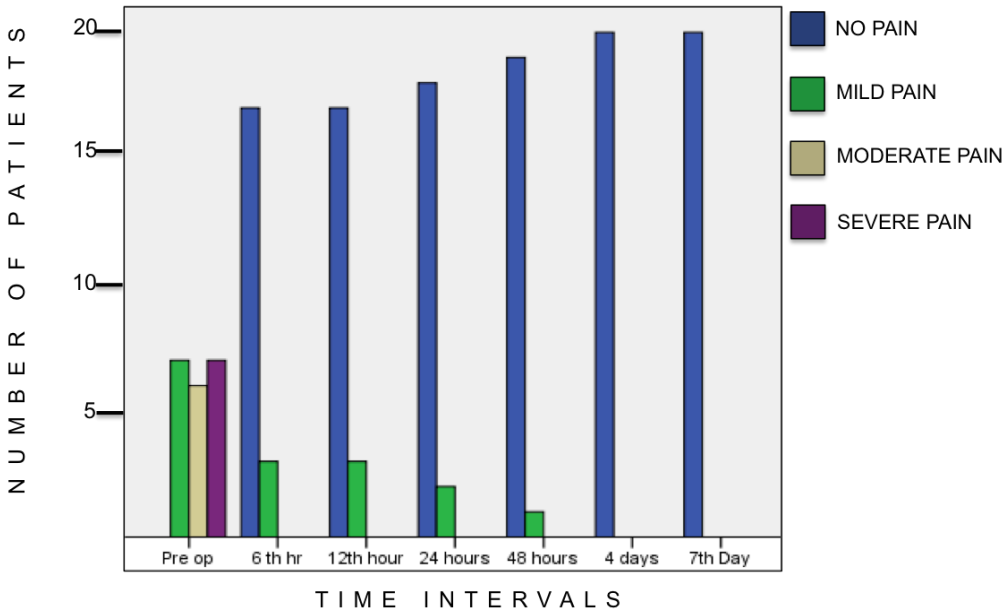
GRAPH 8: 7 DAYS POST OPERATIVE HEFT PARKER VISUAL ANALOGUE SCALE ASSESSMENT



GRAPH 9: CROSS TAB OF CONTROL GROUP



GRAPH 10: CROSS TAB OF EXPERIMENTAL GROUP



Discussion

DISCUSSION

Effective management of pain during and after endodontic procedure is one of the most important goals of treatment. Even with utmost care in performing a root canal treatment, some patients experience pain or flare up after the procedure. This post operative pain is an unpleasant situation for both the dentist and patient. For the long term success of a case, postendodontic pain is considered as a poor indicator. So, the integral part of endodontic treatment must be prevention and management of this post operative pain.[46] Frequency of post endodontic pain ranges between 1.4 to 16% and sometimes up to 50%.[9, 22]

Dental literature is replete with few factors for this incidence of post operative pain. Among the factors include, the gender,[46] type of tooth,[85] single/multiple visits,[2,83] preoperative pain,[66] the vitality of the teeth,[54] various medications used,[49] instrumentation and obturation techniques.[8] Various studies showed that female patients have lesser degree of tolerance to root canal treatment than male patients. This is due to biological differences between genders, due to change in the level of serotonin and non-adrenalin.[18,46] Post endodontic pain after instrumentation is due to the chances of over instrumentation, extrusion of root cleaning and filling materials. [27]

Periradicular inflammation is caused by mechanical, microbial and/or chemical injuries of periapical tissues causing acute inflammation.[27] Inflammation constitutes the body's response to injury and is characterized by

a series of events which includes the inflammatory reaction, a sensory response perceived as pain, and a repair process.[82] The inflammatory reaction is characterized by successive phases- silent phase, vascular phase and cellular phase. A silent phase is where the cells resident in the damaged tissue release the first inflammatory mediators. In the vascular phase, vasodilation and increased vascular permeability occur, and the cellular phase is characterized by the infiltration of leukocytes to the site of injury. The sensory response to inflammation includes pain, hyperalgesia, which is defined as an exaggerated uncomfortable response to a noxious stimulus, and allodynia, which is defined as a nociceptive response to a normally innocuous stimulus. The repair process includes tissue cell division, neovascularization and reinnervation of repaired tissues. [82]

Silent phase is the very first event of inflmmatory reaction. It is based upon the reaction of resident cells of the damaged tissue. Among these resident cells, mast cells and macrophages play a key role in alerting the body to tissue injury, by releasing mediators, such as histamine, kinins, cytokines, nitric oxide (NO), or prostaglandins.

The second phase of the inflammatory reaction, the vascular phase occurs following the release of vasomotor mediators from resident cells. Here, Protease Activating Receptors(PARs) [1,30] plays a prominent role in regulating vascular permeability and motor functions associated with inflammatory response. PARs signal to sensory afferents and induce the release of neuropeptides (substance P and Calcitonin Gene Related Peptide (CGRP)).

These neuropeptides act on vascular beds to induce vasodilatation and increased permeability.[26,78] As a result, these two vascular events provoke plasma leakage from the blood to the inflamed tissues, and inturn facilitate the passage of leukocytes from the blood flow to the tissues, thereby initiating the third phase of the inflammatory reaction: the cellular phase.

The arrival of circulating leucocytes to the site of inflammation marks the beginning of the cellular phase of the inflammatory reaction. In order to be recruited to the site of inflammation, these circulating leukocytes roll onto the venular endothelial surfaces and adhere to the endothelium in order to transmigrate across the endothelial barrier. Several adhesion molecules expressed both by the endothelium and the leukocytes regulate these events of rolling, adhesion, and transmigration. Thrombin is known to induce rolling, adhesion, and transmigration of leukocytes across the endothelium.[82]

Various anti inflammatory drugs are available in the market to control the inflammatory process and relieve pain. In dentistry, several strategies for postoperative pain management were developed including prescribing prophylactic analgesics and corticosteroids, administering long-lasting anaesthesia, root canal preparation using the crown-down technique and occlusal reduction.

Step down or crown down technique produce less incidence of post endodontic pain when compared with step back technique. This may be due to the reason that in the step back technique, there is a high chance of pushing the debris beyond the apical foramen as stated in different studies.[70,7] In the step

down technique, the bulk of tissue debris and microorganisms are removed before apical instrumentation is commenced, which greatly reduces the risks of extrusion causing periapical inflammation.[17] The advent of rotary instruments suggest early coronal flaring. According to Stabholtz at el (1995)[77], the benefits of early coronal flaring include: establishment of an adequate coronal escape route for irrigants and debris, removal of dentin interferences at the canal orifice and cervical third , neutralization and removal of pulp contents from the cervical third before preparing the middle and apical thirds, deeper penetration of the irrigating needle, etc.

Rosenberg et al (1998)[67] stated that occlusal reduction should prevent postoperative pain in those patients whose teeth initially exhibit pulp vitality, percussion sensitivity, preoperative pain, and/or the absence of a periradicular radiolucency. However , recent studies revealed no significant difference in post operative pain following occlusal reduction. [60]

A more recent approach for the management of post operative pain is the use of cryotherapy as put forth by Vera et al (2015).[81] Keskin et al (2016)[35] made a clinical study on the effect of cryotherapy on post operative pain after endodontic treatment. Cryotherapy is a relatively new form of treatment in which the body/organ is briefly exposed to very cold temperatures in order to promote healing and other therapeutic results. It causes reduction in the local blood flow by vasoconstriction and therefore, the local inflammatory reaction, heat experience, and swelling occurs. It also slows the conduction of nerve signals, thereby reducing pain transmission.

Some studies have demonstrated that cryotherapy minimizes secondary hypoxic injury through the reduction of cellular metabolism and decrease in size of damaged area. Cryotherapy has been used for pain relief in sports injuries, tendonitis, runner's knee, arthritis pain, sprains, swelling and pain after a knee or hip replacement, lower back pain and to treat pain or swelling under a cast or a splint.

In dentistry, cryotherapy has been used after intraoral surgical procedures, such as extractions, periodontal surgery, and implant placement, and it was found to be effective in reducing swelling and pain. In endodontics, George et al[28] have found in an in vitro study that the deep dry cryotherapy of NiTi endodontic files can improve its cyclic fatigue resistance, reducing the potential of file separation.

The role of cryotherapy in endodontics was first studied by Vera et al[81] in his invitro study which showed that intracanal delivery of cold saline solution (2.5°C) with negative pressure irrigation reduced the external root surface temperature more than 10°C and maintained it long enough to possibly produce a potential local anti inflammatory effect in the periradicular tissues.[81] The decreased temperature of the external root surface might constrain inflammatory reactions and reduce the production of the release of pain-producing substances, thereby minimizing oedema occurring in the periapical region. Cryotherapy has been shown to decelerate peripheral nerve conduction. As the temperature decreases, the conduction velocity of nerve fibres decreases until it stops completely. However, Ernst and Fialka[23] found

that the nerve conduction of C fibres could not be decreased via the application of moderate cold. Cryotherapy also triggers thermal receptors, which reduce the transmission of painful stimuli. This influence has been referred to as the 'counterirritant effect' and it results in cold-induced neuropraxia.

This study was undertaken to estimate the reduction in root surface temperature following experimental irrigation with cold saline solution on 20 freshly extracted mandibular premolars. After the estimation of the reduction in external root surface temperature, the experimental irrigation was carried out in 20 patients to evaluate the reduction in post operative pain following root surface temperature reduction.

Twenty mandibular premolars extracted for orthodontic reasons or dental caries were collected and stored in distilled water. The ease of availability and common presence of single wide canal were the reasons for preferring this tooth for the present study. Endodontic treatment was initiated on all the teeth samples. Access opening was done with a size 4 round bur. Working length was determined with the apex locator and confirmed radiographically. Biomechanical preparation was carried out with copious irrigation inbetween each instrumentation. 3 % sodium hypochlorite, normal saline and 17% EDTA for 1 min was used for irrigation . Preparation upto 6% 30 was done with Protaper next X3 as per manufacture's instructions.

The samples were kept stable on a putty block and a thermocouple connected to a digital thermometer was placed in contact with the apical 4 mm

of the external root surface. Rubber dam sheet was held in place with the clamp to avoid the irrigant contact with the thermocouple and to prevent bias as suggested by Vera et al.[81] The external root surface temperatures were recorded using the digital thermometer. At first, saline solution at room temperature was irrigated for 5 mins.The external root surface temperature is measured. This was followed by the experimental irrigation with saline at 2.5°C for 5 mins. The temperature on the external root surface was recorded. All the irrigation regimens were done with Endovac negative pressure irrigation system. Normal physiological saline was preferred as it is safe and highly biocompatible when used as an irrigant.

Irrigants hardly reach the root apices because of the vapor lock effect . EndoVac system predictably deliver the irrigant to the apical third of the prepared root canals. De Gregorio[19] et al proved in a series of studies that the use of negative pressure irrigation was the only method for consistently delivering irrigants to the apical third of prepared root canals and not extruding beyond apex. Parente et al[58] proved that the EndoVac system efficiently delivered irrigant to the apical third of root canals when compared with manual, dynamic irrigation with a gutta-percha cone in a closed system model. Conventional needle irrigation has been shown to cause significantly more irrigant extrusion and result in more postoperative pain than negative apical pressure systems.

Saline at 2.5° C is maintained with a help of a frozen bag containing cooling gel. Saline in a bottle is placed in this carrier and its temperature is

monitored using a digital thermometer.

The change in temperature following the control and experimental irrigation were recorded and statistically analysed. Samples with a fall of 10°C for 4 mins in the experimental group was also recorded.

The initial temperature on the external root surface of the collected samples were 20± 2° C. Following irrigation with saline at room temperature, a maximum temperature reduction of 2°C was noted. The experimental irrigation with cold saline solution caused a drop in the external root surface temperature to 8.5 ± 0.5° C within 10 seconds. This drop in temperature was sustained for a period of 4 mins with a change in ±0.5° C.

The thermal properties of dentin - thermal conductivity and thermal diffusivity plays a role in the reduction in external root surface temperature. The thermal conductivity of human dentin has been reported by Lisanti and Zander (2.29 X 10^{-3} cal/sec/cm2/C/cm)[43], Simeral (2.35 X 10^{-3})[74], Phillips,Reinking and Phillips,(0.257 X 10^{-3})[63] and Soyenkoff and Okun (0.96-1.07 X 10^{3}).[76] The thermal conductivity of human enamel has been reported by Soyenkoff and Okun[76] to be 1.55 X 10^{-3}. The thermal diffusivity is the most important thermal parameter when heat conduction is studied. This thermophysical parameter represents the rate between conduction and the material ability to keep the heat. The values of thermal diffusivity for the enamel is 8.4x10^{-3}± 0.1 cm^2/s in the temperature range 200-525° C and for the dentin is 1.5x 10^{-3} ±0.4 cm^2/ s in the temperature range 300-360° C and 2x10^{-3} ± 0.4 for the temperature of 500° C. [62]

This effect of root surface temperature reduction on post operative pain was extrapolated by doing a invivo study on 40 clinical patients. 40 subjects took part in the study, out of which 22 (55%) were male and 18 (45%) were female. The mean age of the participated subjects was 26.81 years with a age range of 20-50 years. There was no deliberate attempt made while choosing the sex or age of the patients during the study. This study is a structured in vivo study to record the post operative pain in humans following root canal treatment.

The Institution Review Board at Ragas dental college and hospitals, Chennai, approved the research protocol. Written informed consent was obtained from all subjects participating in the study. All subjects were given a written consent form either in english or in their regional language and the procedure was clearly explained to them. Only after getting their consent and approval, they were included in the study.

The present study only included mandibular premolar teeth with vital pulps, which were treated in single-visit root canal treatment, to exclude the possible effects of presence of infected necrotic pulps and use of intracanal medicament. Pulpal vitality was confirmed, when there was initial bleeding from the pulp following access cavity preparation, which was visually detected. This excluded false-positive test results of teeth with non-vital pulps, because bleeding has been used as a gold-standard test to ensure pulpal vitality. Health-compromised patients were also not included in the study, because systemic health related factors could interfere with the results.

All patients underwent a pre-established treatment protocol; the only differences were patient-related factors such as gender and tooth type, the distribution of which also showed no significant difference between groups. Preoperative pain levels of the subjects were ascertained using a Heft Parker Visual Analogue scale prior to initiation of the treatment. All patients were administered local anesthesia of 1:80,000 lidocaine with adrenaline via mental nerve block. Tooth was isolated with rubber dam and endodontic treatment was initiated. Access opening was done using air rotor with a size 4 round bur. Working length was determined with the apex locator and confirmed radiographically. Biomechanical preparation was carried out with copious irrigation inbetween each instrumentation. 3 % sodium hypochlorite and 17% EDTA for 1 min was used. Preparation upto 6%, 30 size was done with Protaper next X3 as per manufacturer's instructions. The samples were divided into 2 groups- control (20) and experimental (20).

In the control group, saline solution at room temperature was used for 5 mins as the final irrigating solution. In the experimental group, saline at 2.5°C for 5 mins was used as the final irrigating solution. All the irrigation regimens were done with Endovac negative pressure irrigation system to negate the apical vapour lock effect. Cold microcannulas which were refrigerated till use, was used in the experimental group. This was done to maintain the cold temperature during final irrigation. Obturation was carried out with gutta percha points and zinc oxide eugenol sealer. Access cavity was immediately sealed with zinc oxide eugenol cement and after 1 week, were

sealed by employing sandwich technique of a base with glass ionomer cement followed by composite restoration.

All subjects on reaching home, were asked to rate their pain on an Heft Parker Visual Analogue Scale. HP VAS used was a 170-mm line with various descriptive terms. The subjects placed a mark on the scale where it best described their pain level at different time intervals- 6 hours post op, 12 hours post op, 24 hours post op, 48 hours post op, 4 and 7 days post op. To interpret the data, the VAS was divided into following 4 categories: no pain correspond to 0 mm on the scale; mild pain was defines as >0mm and <54mm, which included descriptors of faint, weak and mild pain; moderate pain was defined as >54mm and <114mm; severe pain was defined as ≥114mm and included the descriptors of strong, intense and maximum possible pain.

Preoperative pain levels among the samples ranged from mild (in 14 patients), moderate (in 12) and severe (in 14). They were divided into 2 groups- control (mild-7, moderate-6, severe-7) and experimental group (mild-7, moderate-6, severe-7). On clinical examination, decay, pain on probing, tenderness to percussion was present. On radiographic examination, it showed radiolucency involving / approximating the pulp. None of the patients took analgesics / antibiotics to relieve pain

In the control group at 6 hours post operative, where saline at room temperature was used as the final irrigant, 8 (40%) patients experienced no pain, 7 (35%) experienced mild pain and 5 (25%) experienced moderate pain. None of the patients took analgesics for pain control

In the experimental group at 6 hours post operative, where cold saline at 2.5°C was used as the final irrigant, 17 (85%) patients experienced no pain, 3 (15%) experienced mild pain. None of the patients took analgesics for pain control

At 12 hour post operative in control group, 8 (40%) patients had no pain, 6 (30%) experienced mild pain and 6 (30%) experienced moderate pain. One patient from the mild pain category reported a slight increase in pain which falls under moderate level. In the experimental group, 17 (85%) patients experienced no pain, 3 (15%) experienced mild pain

At 24 hour post operative in control group, 8 (40%) patients experienced no pain, 7 (35%) experienced mild pain and 5 (25%) experienced moderate pain. The patient who shifted from mild to moderate pain, again dropped to mild pain level at 12 hours post op. In the experimental group, in addition to 17 patients in no pain group, one patient from mild pain reported with no pain at 12 hour post op (90%). 2 patients (10%) reported with mild pain

At 48 hours post operative, 9 (45%) patients experienced no pain, 8 (40%) experienced mild pain and 3 (15%) experienced moderate pain in control group. In experimental group, 19 (95%) patients had no pain and one patient (5%) had mild pain

At 4 days post operative, 14 (70%) patients had no pain and 6 (30%) patients had mild pain in control group. In the experimental group, all patients had no pain

At 7 days post operative, 18 (90%) patients had no pain and 2 (10%) patients had mild pain in control group. In the experimental group, the perception of no pain remained the same.

It was noted that the intensity of pain was significantly different at 6,12,24,48 hours post operative and on 4 days. 7 days post op has no significant difference between the groups.

Comparison of pain intensity at different time intervals in the control group showed that the intensity of pain reduced gradually over time. On 4th day post operative, 14 patients had no pain and 6 patients had mild pain. At 7th day post operative, 2 patients from mild pain reported of no pain.

On comparing the pain intensity at various time intervals in the experimental group, there was a significant reduction in intensity of pain. At 6 hours post operative, 17 patients reported with no pain and 3 patients had mild pain. By 4 days, all patients were free of pain.

Comparison of post operative pain levels of patients in control group and experimental group at 6, 12, 24, 48 hours ,4 days and 7 days showed that there was greater and faster reduction in pain intensity in experimental group than in control group.

The first clinical study conducted on the effect of intracanal cryotherapy in endodontics was by C Keskin., *et al*. (2016)[35] who assessed the effect of 2.5°C cold saline irrigation as a final irrigant following biomechanical preparation of root canals on postoperative pain in patients with irreversible pulpitis. In this study, the effect of intracanal cryotherapy was

evaluated by delivering the cold saline solution using conventional needle irrigation with side-vented 31 G NaviTip needle. The needle was inserted 2 mm short from working length, during the root canal treatment of all patients. The authors reported that, there was a significant pain reduction levels when compared to that of a control group . However, a recent clinical study by Al-Nahlawi., *et al*. (2017)[6] showed that intracanal cryotherapy along with negative pressure irrigation system reduced post operative pain. This may be due to less irritation due to minimal debris extrusion and more cleaning possibility by the endovac irrigation system as it works like a closed model system as mentioned earlier.

The present study showed that root surface temperature plays a vital root in manifestation of .post operative pain. Cryotherapy reduced postoperative pain following single-visit root canal treatment in teeth with vital pulps probably by reducing external root surface temperature.

It is widely believed that the therapeutic application of cryotherapy leads to a reduction in pain and swelling. Saeki[71] and other authors stated that pain relief with cold application could be due to many mechanisms including altered nerve conduction velocity (NCV), vasoconstriction, inhibition of nociceptors, a reduction in muscle spasms and/or a reduction in metabolic enzyme activity levels[3]. Cryotherapy could also be effective as a counterirritant to pain through diffused noxious inhibitory controls, pain gate theory, suppressed nociceptive receptor sensitivity or via the analgesic descending pathway of the central nervous system such as endorphins [89]

The structural integrity of a tissue is affected after an injury. For example, the rupture of the cellular membrane may lead to cellular death. This characterizes the primary event of the injury process.[50] A physiological response from metabolic and enzymatic mechanisms is activated in order to restore the integrity of the injured area. The second phase (secondary injury) is characterized by oxidative stress. There is decrease in oxidative support due to impairment of blood vessels. This ischemic period can cause the death of healthy cells in adjacent area of the injured site. Tissue cooling is commonly used after injuries in order to decrease negative effects caused by secondary cell hypoxia. It decreases the metabolic activity in damaged tissues and thus promotes survival of tissues subjected to an environment with low oxygen supply.

Treatment with tissue cooling decreases oxidative damages caused by inflammatory response. Previous studies showed a decrease in blood flow to 50% of the basal blood supply secondary to local vasoconstriction. This reduces pro inflammatory substances that appear in blood circulation of the affected area, thereby restricting the development of injury. Furthermore, cryotherapy is also relieves pain through a sensibility decrease of nocioceptive sensory nerves. This allows for the recovery of pain-free movements and accelerates the healing process.

Pain is associated with the presence of high levels of inflammatory agents in affected tissues.[44] PGE-2 is one such agent which is produced by inflammatory cells (e.g., macrophages) and fibroblasts in response to tissue

injury.[5] PGE-2 is a highly active inflammatory molecule that causes pain and induces vasodilatation ,hyperalgesia ,and fever.[13]

Cold treatment reduces PGE-2 production and COX-2 protein expression. Although many NSAIDs targeting COX-2 are used in clinical settings to reduce pain caused by injury, the findings of the study conducted by Zhang et al (2014)[86] justified the application of cold treatment as a safe alternative, Cold treatment may also reduce pain by decreasing the high levels of COX-2 and subsequent PGE-2 production associated with injury. [86]

In the study conducted by Algafly et al (2007)[3], nerve conduction velocity is significantly and progressively reduced concomitantly with skin temperature during cryotherapy. Associated with the changes in nerve conduction velocity, they observed significant increases in pain threshold and pain tolerance. They reported an average reduction of 33% in nerve conduction velocity ,which equates to a 0.4 m/s decrease in sensory nerve conduction velocity for each 1°C fall in skin temperature . Reid *et al* [65] reported that low temperature could increase the friction between Ca^{2+} and its cellular "gate" during the exchange that could result in the delay of action potential generation.

Probably, in this present study, the application of cold therapy or cryotherapy would have produced similar effects ,thereby reducing the onset of pain after the clinical procedure. In light of these results, since both invitro and clinical study showed a reduction in temperature and decrease in intensity of pain respectively, the null hypothesis stands rejected. This present study

proved that there is concomitant reduction in temperature which in turn resulted in reduction of post operative pain.

Hence, it can be stated that the use of cryotherapy can serve as a simple, cost-effective, and non-toxic option for postoperative pain control following single visit root canal treatment. Further studies in this field is necessary to approve the use of cryotherapy in clinical practice.

Summary

SUMMARY

This study was performed to compare and evaluate the external root surface temperature reduction following cold saline irrigation -invitro and to extrapolate this temperature change on the post operaive pain following single visit root canal treatment-invivo.

40 freshly extracted human mandibular premolars with single root and root canal were selected. Access was gained with a size 4 round bur followed by determination of working length. All the samples were instrumented upto the working length with Protaper Next X3 30/0.06.

After cleaning and shaping, each specimen was mounted on a block to hold it in place. The tooth was isolated with a rubber dam. The changes in the external root surface temperature before and after final irrigation was recorded with the help of Type K thermocouples RoHs compliant connected to a digital thermometer, attached to the apical 4 mm of the root surface. The samples were divided into 2 groups - control group(20), experimental group (20). Final irrigation was performed with saline at room temperature in the control group and cold saline at 2.5° C in the experimental group. Irrigation was done with endovac irrigation system for 5 minutes. The obtained results showed that, there was a significant reduction in external root surface temperature following cold saline irrigation .

To extrapolate these results on the post operative pain following single visit root canal treatment, 40 patients with symptomatic irreversible pulpitis were chosen. Patients were asked to record their preoperative pain levels on Heft parker Visual Analogue Scale.

The same procedure as done in the invitro study was carried out in both the control and experimental groups. The post operative pain levels at 6 hours, 12 hours, 24 hours ,48 hours , 4 days and 7 days were also recorded on Heft Parker VAS scale. Root canal was obturated with gutta percha points and zinc oxide eugenol sealer. Access cavities were sealed temporarily with zinc oxide eugenol folowed by the final restoration with glass ionomer cement and composite resin employing sandwich technique.

The results were tabulated and statistically analysed after 6,12,24,48 hours ,4^{th} day and 7^{th} day of treatment for post operative pain .

Conclusion

CONCLUSION

The present study was carried out to evaluate the reduction in root surface temperature following final irrigation with cold saline - invitro and extrapolating its effects to the intensity of post operative pain following single visit root canal treatment in patients with acute irreversible pulpitis.

Within the limitations of the present study , it was concluded that

In invitro study,

1. The external root surface temperature in mandibular premolars, measured with a digital thermometer, prior to endodontic treatment, showed a mean temperature of 21.1°C
2. The mean external root surface temperature after using normal saline as final irrigant was 19.2°C.
3. The mean external root surface temperature after using cold saline as final irrigant was 8.7°C.
4. The external root surface temperature before and after using normal saline as final irrigant showed an average 2° C drop in temperature.
5. Temperature on external root surface before and after using cold saline at 2.5 °C as final irrigant showed an average temperature reduction of 12° C.
6. The temperature difference after using normal saline and cold saline showed a diference of 9°C.

7. The drop in temperature was statistically significant for cold saline irrigation (experimental group) with normal saline irrigation (control group).

In invivo study,

8. The invivo evaluation using Heft Parker Visual Analogue scale showed pre operative pain levels as mild , moderate or severe among the patients studied, with acute irreversible pulpitis.
9. Estimation of post operative pain using HPVAS in control group (normal saline used as final irrigant) at the end of 6 hours of single visit endodontic treatment showed 8 patients with no pain, 7 patients with mild pain and 5 patients with moderate pain.
10. On comparison , there was gradual decrease in pain at the end of 12,24,48 hours,4 days and 7 days. The pain intensity of 5 patients with moderate pain reduced to mild pain at the end of 4 days. Out of 7 patients with mild pain, there were no pain in 6 patients and mild pain continued for one patient at the end of 4 days. At the end of 7 days, 18 patients had no pain and 2 patients had mild pain.
11. Estimation of post operative pain in mandibular premolars at the end of 6 hours after endodontic treatment in experimental group (cold saline at 2.5 ° C used as final irrigant) revealed 17 patients with no pain and 3 patients with mild pain.

12. On comparison within this experimental group, pain levels progressively reduced and at 4 days post operative, all 20 patients in the experimental group were free of pain.
13. Comparison of post operative pain levels of patients in control group and experimental group at 6, 12, 24, 48 hours ,4 days and 7 days showed that there was greater and faster reduction in pain intensity in experimental group than in control group.
14. Comparison of control and experimental group values showed significant difference at 6,12,24,48 hours and 4 days and without any significant difference at the end of 7^{th} day. Use of normal saline as irrigant reduced the pain intensity slowly, whereas the use of cold saline, totally abolished pain by the end of 4^{th} day. All patients except 2, did not have any pain at the end of 7^{th} day.

Use of cold saline solution as final irrigant prior to root canal obturation probably lowers the inflammatory reaction around the external root surface. This inturn reduces the post operative pain following root canal treatment and would eliminate the need for analgesics.

Final irrigation with cold saline solution seems to be the panacea for the control of post endodontic pain.

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Annexures

Annexure-I

S. no	Age in years	Group	HPVAS assessment for pain intensity						
			Pre-op	6 hours post-op	12 hours post-op	24 hours post-op	48 hours post-op	4 days post-op	7 days post-op
1	22/M	Control	Mild	No pain	No pain	No pain	No pain	No pain	No pain
2	34/M	Control	Moderate	Mild	Mild	Mild	No pain	No pain	No pain
3	36/F	Control	Mild	No pain	No pain	No pain	No pain	No pain	No pain
4	47/F	Control	Moderate	No pain	No pain	No pain	No pain	No pain	No pain
5	48/F	Control	Severe	Moderate	Moderate	Moderate	Mild	No pain	No pain
6	43/M	Control	Mild	No pain	No pain	No pain	No pain	No pain	No pain
7	34/M	Control	Severe	Moderate	Moderate	Moderate	Mild	Mild	No pain
8	46/F	Control	Moderate	Mild	Moderate	Mild	Mild	No pain	No pain
9	32/F	Control	Mild	No pain	No pain	No pain	No pain	No pain	No pain
10	21/M	Control	Moderate	Mild	Mild	Mild	Mild	No pain	No pain
11	25/M	Control	Mild	No pain	No pain	No pain	No pain	No pain	No pain
12	47/M	Control	Moderate	Mild	Mild	Mild	Mild	No pain	No pain
13	46/M	Control	Severe	Moderate	Moderate	Moderate	Moderate	Mild	Mild
14	21/M	Control	Moderate	Mild	Mild	Mild	Mild	Mild	No pain
15	20/M	Control	Severe	Moderate	Moderate	Moderate	Moderate	Mild	No pain
16	39/M	Control	Mild	No pain	No pain	No pain	No pain	No pain	No pain
17	39/F	Control	Severe	Mild	Mild	Mild	Mild	Mild	No pain
18	40/F	Control	Severe	Moderate	Moderate	Moderate	Moderate	Mild	Mild
19	21/F	Control	Mild	No pain	No pain	No pain	No pain	No pain	No pain
20	28/F	Control	Severe	Mild	Mild	Mild	Mild	No pain	No pain
21	37/M	Experimental	Mild	No pain	No pain	No pain	No pain	No pain	No pain
22	38/M	Experimental	Moderate	No pain	No pain	No pain	No pain	No pain	No pain
23	24/M	Experimental	Severe	Mild	Mild	No pain	No pain	No pain	No pain
24	49/M	Experimental	Moderate	No pain	No pain	No pain	No pain	No pain	No pain
25	28/F	Experimental	Severe	Mild	Mild	Mild	No pain	No pain	No pain
26	31/F	Experimental	Mild	No pain	No pain	No pain	No pain	No pain	No pain
27	30/M	Experimental	Severe	No pain	No pain	No pain	No pain	No pain	No pain
28	29/M	Experimental	Severe	No pain	No pain	No pain	No pain	No pain	No pain
29	32/M	Experimental	Mild	No pain	No pain	No pain	No pain	No pain	No pain
30	20/F	Experimental	Severe	Mild	Mild	Mild	Mild	No pain	No pain
31	21/F	Experimental	Mild	No pain	No pain	No pain	No pain	No pain	No pain
32	48/F	Experimental	Moderate	No pain	No pain	No pain	No pain	No pain	No pain
33	28/F	Experimental	Mild	No pain	No pain	No pain	No pain	No pain	No pain
34	39/F	Experimental	Moderate	No pain	No pain	No pain	No pain	No pain	No pain
35	38/M	Experimental	Severe	No pain	No pain	No pain	No pain	No pain	No pain
36	45/M	Experimental	Mild	No pain	No pain	No pain	No pain	No pain	No pain
37	34/M	Experimental	Severe	No pain	No pain	No pain	No pain	No pain	No pain
38	23/M	Experimental	Moderate	No pain	No pain	No pain	No pain	No pain	No pain
39	29/F	Experimental	Mild	No pain	No pain	No pain	No pain	No pain	No pain
40	45/F	Experimental	Moderate	No pain	No pain	No pain	No pain	No pain	No pain

Annexure-II

Consent form

I ---------- hereby acknowledge that my doctor has explained to me that I will have to undergo root canal treatment, with local anesthesia in the particular region. He/she also explained to me about the expected treatment outcome and what could happen if my condition remains untreated.

I also understand that local anesthesia is needed, so that my doctor can perform the procedure. It has been informed that all forms of anesthesia involves certain risks. Certain possible risks exists, that although rare, could include pain, swelling, bleeding tendency, infection, nerve damage, and some unexpected reactions

Root canal treatment involves removal of the decayed portion of the teeth, followed by cleaning of the root canals with the specific instruments for cleaning and shaping. Irrigation of the root canals are done following each instrumentation to remove the debris from the root canals. This is followed by filling of the root canal system.

The aim is to evaluate the post operative pain following the use 2.5-4°C cold saline solution as a final irrigant in single visit root canal treatment .

The procedure has been explained to me by the doctor. The merits and demerits, the possible outcomes of the procedure has been explained.

I acknowledge that I have admitted all my medical conditions and the medicines taken by me for the same without hiding anything.

I certify and acknowledge that I have read this form or had it read to me, that I understand the risks, alternatives and expected results of the treatment; and that I had ample time to ask questions and to consider my decision.

Date and time: **Patient's signature:**

Substitute's signature: **Witness:**

Relationship to patient:

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness_____
Thumb print of participant
Signature of witness _____
Date _____

Day/month/year

Annexure-III

ஒப்புதல் படிவம்

திரு/ திருமதி _____ என்கிற நான், எனது மருத்துவர் என்னன குறிப்பிட்ட பற்களுக்கு வேர் சிகிச்சை உள்ளூர் மயக்க மருந்தின் கீழ் செய்து கொள்ளும்படி கேட்டு அறிவுருத்தினார். வேர் சிகிச்சையின் பலன்கள் மற்றும் சிகிச்சை செய்யாமல் இருப்பதினால் வரும் விளைவுகளையும் கூறினார்.

இந்த சிகிச்சை செய்வதற்கு உள்ளூர் மயக்க மருந்து அளிப்பது கட்டாயம் என்பதை நான் அறிவேன். உள்ளூர் மயக்க மருந்தினால் சில பின் விளைவுகள் வரகூடும் என்பதை உணர்கிறேன். அரிதாக வலி, வீக்கம், நோய் தொற்று, இரத்தப்போக்கு, நரம்பு தளர்ச்சி மற்றும் மருந்து ஒவ்வாமை ஏற்படலாம் என்பதையும் அறிவேன்.

வேர் சிகிச்சை என்பது பல் சிதைவு ஏற்பட்ட பகுதியை அகற்றுதல், பின்னர் வேர் பகுதியினை சிறப்பு உபகரணம் கொண்டு சுத்தம் மற்றும் வடிவமைத்தல், சுத்தம் செய்தல், வேர்களை அடைத்தல் ஆகிய கூட்டு சிகிச்சை என்பதை அறிவேன்.

இந்த ஆய்வின் நோக்கம், 2.5 - 4° C குளிர்ந்த உப்பு நீர் கொண்டு சுத்தம் செய்வதனால் சிகிச்சைக்கு பின் வலியின் தன்மையை அளவு செய்தல் என்பதை மருத்துவர் என்னிடம் கூறினார். அதன் நன்மைகள் மற்றும் தீமைகள் தெளிவாக மருத்துவர் எடுத்துரைத்தார்.

என்னுடைய உடம்பில் உள்ள நோய்கள் மற்றும் நான் உட்கொள்ளும் மருந்துகள் பற்றிய முழு விவரங்களும் மருத்துவரிடம் ஒளிவு மறைவின்றி கூறிவிட்டேன்.

இந்த ஒப்புதல் படிவத்தில் உள்ள எல்லாவற்றையும் நான் நன்கு அறிந்து கொண்டேன். மற்றும் சிகிச்சையின் நலன்கள் மற்றும் விளைவுகள் பற்றி நன்கு தெரிந்து கொண்டேன். சிகிச்சையினால் வரும் பிரச்சனைகளை மருத்துவரோ, ஆசிரியர்களோ, கல்லூரியோ பொறுப்பு அல்ல என்பதை அறிவேன்.

சாட்சி:

நோயாளியின் உறவுமுறை: கையொப்பம்

படிக்க தெரியாதவர்கள்:

படிக்க தெரிந்தவர்கள் கையொப்பம் இட வேண்டும்.

(முடிந்தால், இந்த நபர் நோயாளியால் தேர்ந்தெடுக்கப்பட்டவராகவும், ஆராய்ச்சி குழுவிற்கு தொடர்பில்லாமலும் இருக்க வேண்டும்). படிக்க தெரியாதவர்கள் பெருவிரல் ரேகையும் இட வேண்டும்.

நான் ஒப்புதல் படிவத்தை நோயாளி படிப்பதையும், நோயாளியின் கேள்விகளுக்கு மருத்துவர் விடை அளித்தமைக்கும் சாட்சி ஆவேன். மற்றும் நோயாளி சிகிச்சைக்கு சம்மதம் தெரிவிக்க எந்த நிர்பந்தம் அளிக்கப்படவில்லை என்பதையும் உறுதி கூறுகிறேன்.

சாட்சியின் பெயர்:

சாட்சியின் பெருவிரல் ரேகை பதிவு:

சாட்சியின் கையொப்பம்:

Annexure-IV

Name: Date:

Age: Gender: OP num:

Chief complaint:

Past medical history:

Intraoral examination:

Radiographic examination:

Diagnosis:

Treatment plan:

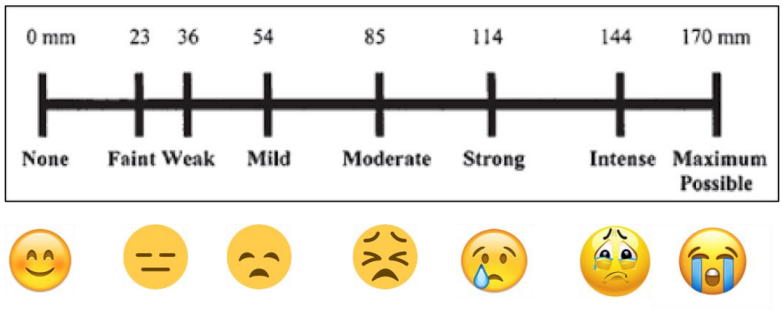
Final irrigation solution used during root canal treatment :

Normal saline ☐

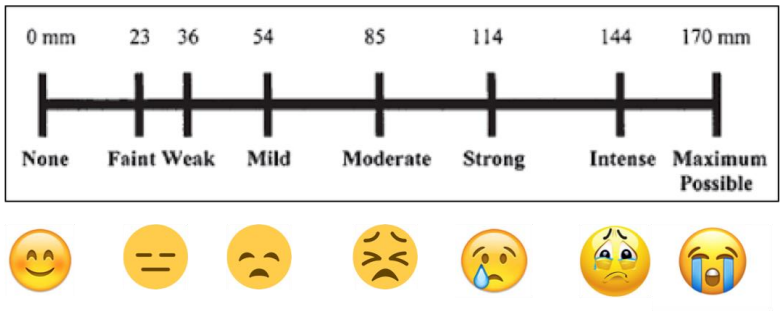
Cold saline ☐

HEFT PARKER VISUAL ANALOGUE SCALE ASSESSMENT

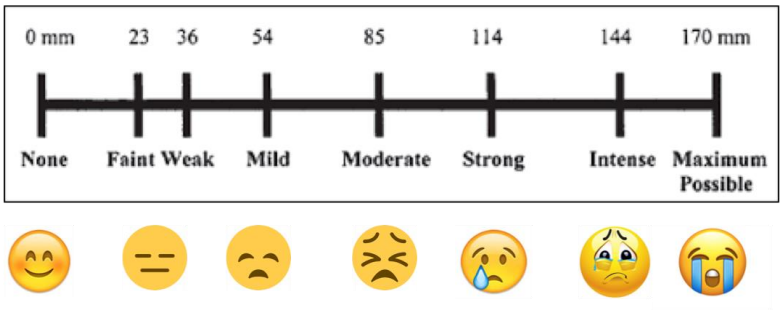
Preoperative pain assessment



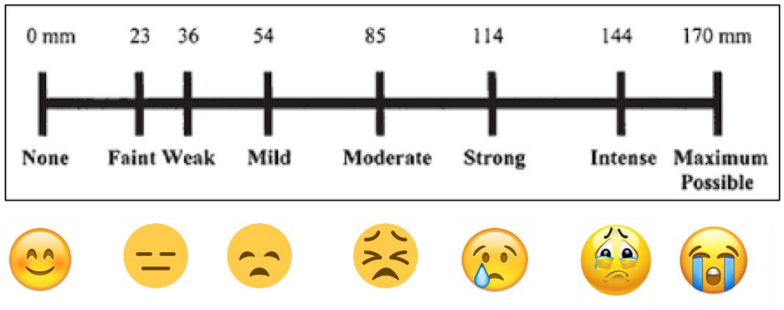
Postoperative pain assessment 6 hours after root canal treatment



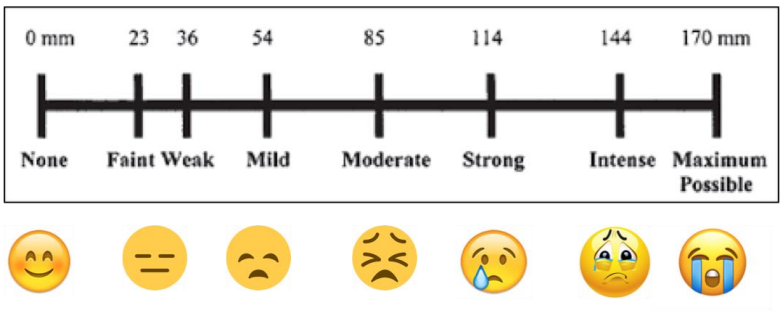
Postoperative pain assessment 12 hours after root canal treatment



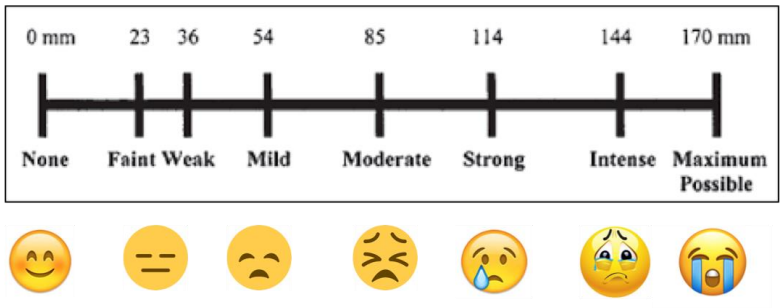
Postoperative pain assessment 24 hours after root canal treatment



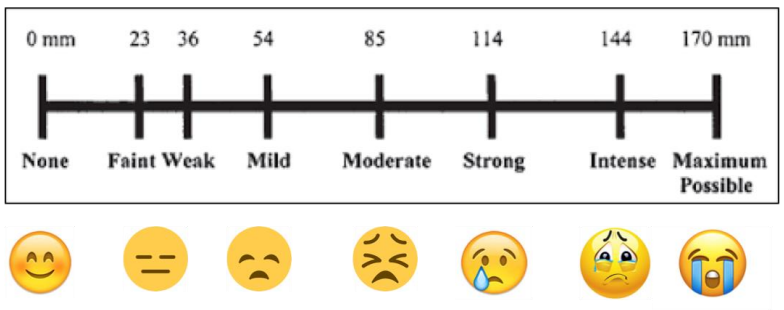
Postoperative pain assessment 48 hours after root canal treatment



Postoperative pain assessment 4 days after root canal treatment



Postoperative pain assessment 7 days after root canal treatment



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Date: 11.1.2018

Place: Chennai

From
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The dissertation topic titled **"EFFECT OF COLD SALINE SOLUTION AS FINAL IRRIGANT ON POSTOPERATIVE PAIN AFTER SINGLE VISIT ROOT CANAL TREATMENT – AN INVIVO STUDY"** submitted by **Dr. SHRI NANDHINI DEVI.R** has been approved by the Institutional Review Board of Ragas Dental College & Hospital.

Dr. N.S. AZHAGARASAN, M.D.S.,
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